



December 28, 2016

Lt. Brian Andrews-Shigaki
Office Warfighter Performance S&T Dept
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: Final Technical Report with SF298 by the National Marrow Donor Program®
Reference: Grant #N00014-14-1-0848 between the Office of Naval Research and the National Marrow Donor Program

Dear Lt. Andrews-Shigaki,

In accordance with the requirements of the Referenced Office of Naval Research Grant, the National Marrow Donor Program® (NMDP) hereby submits the required Final Technical Report for the period of September 15, 2014 through September 30, 2016. Delivery of this report completes all actions required under the referenced Grant.

Should you have any questions regarding the performance activity of under this Grant, you may contact our Chief Medical Officer – Dennis Confer, MD directly at 763-406-3425.

Please direct any contractual questions pertaining to the Grant to my attention at 763-406-3403 or to cabler@nmdp.org.

Sincerely,

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Contracts Manager

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REPORT DOCUMENTATION PAGE

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DEVELOPMENT OF MEDICAL TECHNOLOGY

FOR CONTINGENCY RESPONSE TO MARROW TOXIC
AGENTS

FINAL BENEFITS REPORT

September 15, 2014 – September 30, 2016



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I. Heading

PI: Dennis L. Confer, M.D.

National Marrow Donor Program

N00014-14-1-0848

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

II. Scientific and Technical Objectives

The main objective of this grant is to develop, test and mature the ability of the National Marrow Donor Program® (NMDP) to address contingency events wherein civilian or military personnel are exposed to marrow toxic agents, primarily ionizing radiation or chemical weapons containing nitrogen mustard. An accident, a military incident, or terrorist act in which a number of individuals are exposed to marrow toxic agents will result in injuries from mild to lethal.

Casualties will be triaged by first responders, and those with major marrow injuries who may ultimately be candidates for hematopoietic cell transplantation (HCT) will need to be identified. HCT donor identification activities will be initiated for all potential HCT candidates. NMDP-approved transplant centers will provide a uniform and consistent clinical foundation for receiving, evaluating and caring for casualties. NMDP coordinating center will orchestrate the process to rapidly identify the best available donor or cord blood unit for each patient utilizing its state-of-the-art communication infrastructure, sample repository, laboratory network, and human leukocyte antigen (HLA) expertise. NMDP's on-going immunobiologic and clinical research activities promote studies to advance the science and technology of HCT to improve outcomes and quality of life for the patients.

III. Approach

A. Contingency Preparedness

HCT teams are uniquely positioned to care for the casualties of marrow toxic injuries. The NMDP manages a network of centers that work in concert to facilitate unrelated HCT. The Radiation Injury Treatment Network (RITN), comprised of a subset of NMDP's network centers, is dedicated to radiological disaster preparedness activities and develops procedures for response to marrow toxic mass casualty incidents.

B. Development of Science and Technology for Rapid Identification of Matched Donors

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Disease stage at the time of transplantation is a significant predictor of survival, decreasing the time to identify the best matched donor is critical. Methods are under development to rapidly provide the best matched donor for HCT.

C. Immunogenetic Studies in Transplantation

Improving strategies to avoid and manage complications due to graft alloreactivity is essential to improve the outcomes of HCT. Research efforts are focused on strategies to maximize disease control while minimizing the toxicity related to alloreactivity in HCT.

D. Clinical Research in Transplantation

Clinical research creates a platform that facilitates multi-center collaboration and data management to address issues important for managing radiation exposure casualties. Advancing the already robust research capabilities of the NMDP network will facilitate a coordinated and effective contingency response.

IV. Concise Accomplishments

- a. Contingency Preparedness
 - i. Bi-annual RITN conference entitled, “Medical and Organizational Challenges Resulting from a Biological/Nuclear Emergency” held in Rockville, MD on July 14-15, 2015.
 - ii. Facilitated a web-based table top exercise on July 22, 2015.
 - iii. Supported regional table top exercises in Seattle and Salt Lake City.
 - iv. Executed three full scale functional exercises at the University of Colorado, University of West Virginia and Wake Forest University.
- b. Development of Science and Technology for Rapid Identification of Matched Donors
 - i. Supported the HLA typing of approximately 110,000 newly recruited donors (102% minority race/ethnicity).
 - ii. Search Prognosis Genotype Frequency study accepted for publication and prototype online tool that provides search prognosis results (good, fair and poor) released.
- c. Immunogenetic Studies in Transplantation
 - i. Completed high resolution HLA and presence/absence KIR genotyping on 1,000 unrelated donor/recipient pairs.
 - ii. Presented 3 oral abstracts at the International KIR Workshop
 - iii. Launched a pilot project to evaluate the clinical benefits of matching for full HLA gene sequences.

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- iv. Implemented two web-services for research; one for HLA validation and another for HLA match assessment.
- d. Clinical Research in Transplantation
 - i. Published 196 peer reviewed manuscripts and presented 85 abstracts at national/international meetings.
 - ii. Completed the development of the RITN data collection forms and released in the CIBMTR FormsNet application.

V. Expanded Accomplishments

Contingency Preparedness

Maintain the Radiation Injury Treatment Network (RITN) to prepare for the care of patients resulting from a hematopoietic toxic event.

Hospitals are eligible to join RITN if they participate in both the NMDP Network of treatment centers and the NDMS. The NDMS is comprised of over 1,800 accredited hospitals across the nation that have agreed to receive trauma casualties following a disaster. The program is managed by the Department of Health and Human Services. RITN conducts targeted recruitment on an annual basis with a goal of expanding the network. During the project period, six new transplant centers joined RITN; resulting in a total composition of: 64 transplant centers, 5 donor centers, and 6 cord blood banks (Figure 1). The new centers that joined RITN were:

1. Scripps Green Hospital (CA)
2. New York University (NYU)-Langone Medical Center (NY)
3. Children's of AL (AL)
4. Spectrum Health (MI)
5. Roswell Park Cancer Institute (NY)
6. University of Pennsylvania Medical Center (UPMC) (PA)

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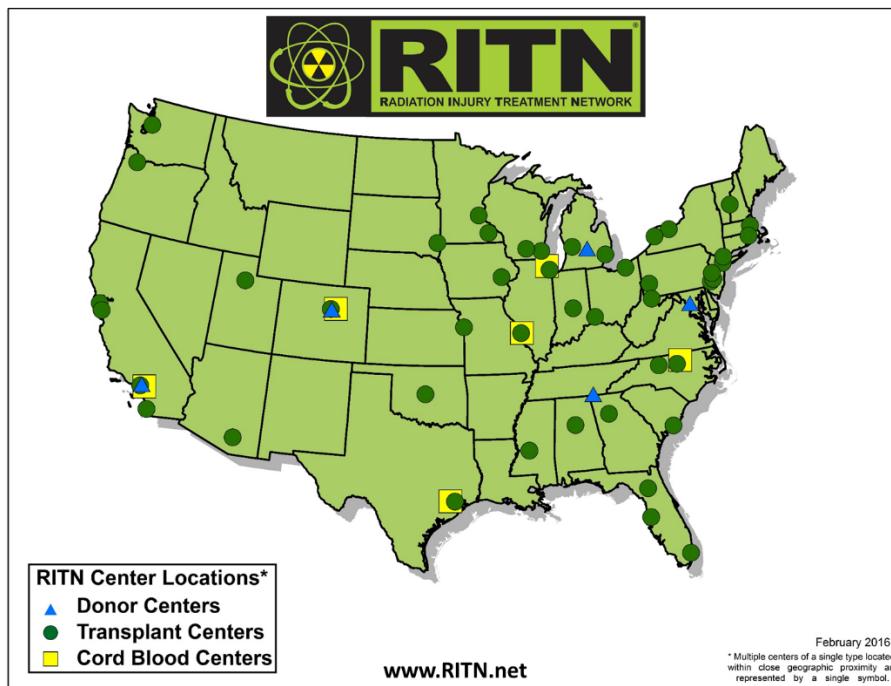


Figure 1. Location of RITN Centers

2015 Biennial RITN conference:

The focus of the conference held in Bethesda, MD on July 14 and 15, 2015 was Medical and Organizational Challenges Resulting from a Radiological/Nuclear Emergency. A total of 150 people attended with an additional 37 invited speakers. The conference format consisted of two tracks; research updates and operational lessons learned. The operational track was heavily attended and received laudatory comments from all attendees. Speakers focused on lessons learned from implementing radiological response plans to lessons learned from radiological response exercises. The conference agenda is available on the [RITN Web site](#) for reference.

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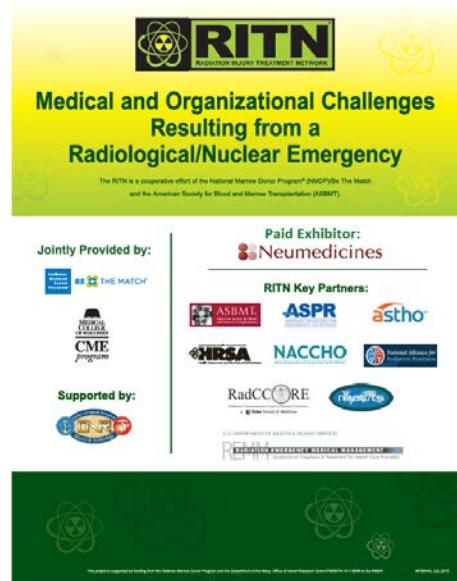


Figure 2. RITN Biennial conference flyer

RITN Preparedness Activities

RITN centers were asked to continue to develop their level of preparedness during 2015. Tasks included communications drills, updating of standard operating procedures, outreach to local public health and emergency management contacts, a tabletop exercise and training of staff.

During 2015, 98% of RITN centers completed all of their required annual tasks (Figure 3). This is consistent with the performance during the previous year.

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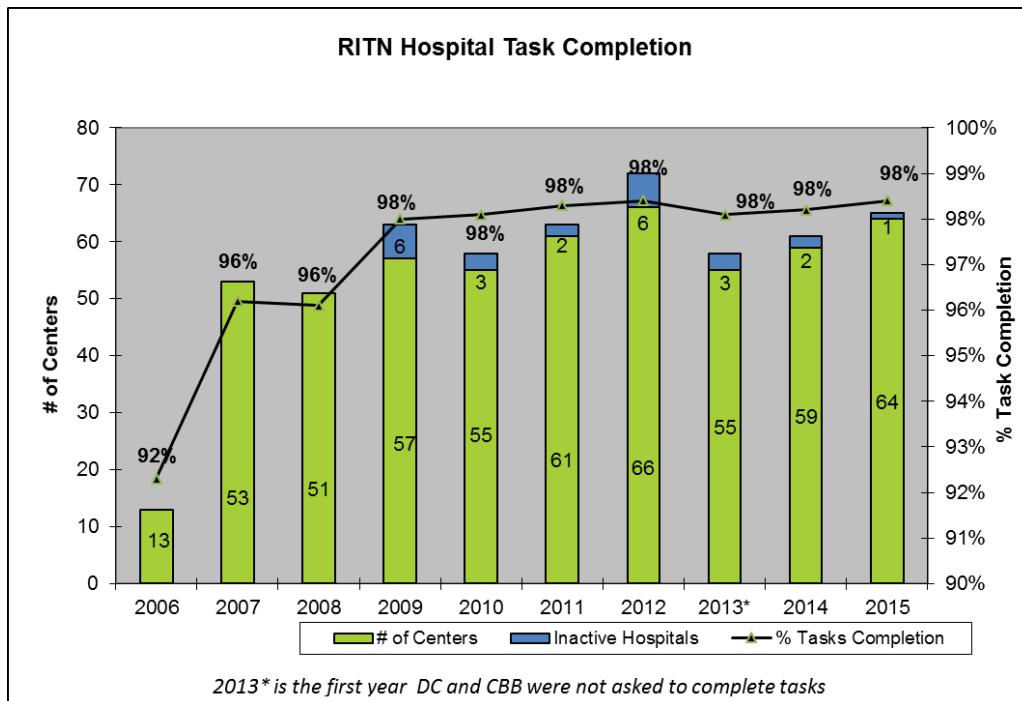


Figure 3. RITN annual training task completion rates by year

RITN Exercise Program: RITN coordinates or provides support for many radiological exercises each year; these include full-scale, functional, regional tabletop and tabletop exercises (the intensity and effort required decreases accordingly from full-scale to tabletop). RITN has facilitated more than 505 exercises since initiation in 2006 (see Figure 10 for breakdown by type). During 2015 Dana-Farber Cancer Institute held a full-scale radiological exercise in Boston and Memorial Sloan Kettering Cancer Center conducted a regional tabletop exercise. Both were great successes.

- Coordination and funding of radiological incident exercises:
 - Regional tabletop exercises in:
 - Chicago
 - Southern Minnesota
 - Salt Lake City
 - Seattle
 - Full-scale exercises in:
 - Denver
 - West Virginia
 - North Carolina
 - 6 web based tabletop exercises
 - Annual RITN tabletop exercise conducted by 57 hospitals, the majority conducted by a RITN facilitator via web based format
 - After Action Review reports are posted on RITN.net

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These exercises involved many external partners necessary for the response including:

- Adams County Office of Emergency Management
- Chicago Department of Public Health
- Chicago Office of Emergency Management and Communications
- City of Aurora Office of Emergency Management
- Colorado State Department of Health
- Federal Coordinating Center – NDMS
- Harborview Medical Center
- Illinois Department of Public Health
- Illinois Emergency Management Agency
- Medical Reserve Corps
- National Association of County and City Health Officials (NACCHO)
- National Disaster Medical System
- National Institutes of Health
- Northwest Healthcare Response Network
- Public Health Seattle King County
- Salt Lake City Fire Department
- Salt Lake City Health Department
- Seattle Children's Hospital
- Seattle Fire Department
- Seattle Medic One EMS
- Tri-County Health
- U.S. Centers for Disease Control and Prevention
- U.S. Department of Health and Human Services-Assistant Secretary for Preparedness and Response
- U.S. Veterans Administration Medical Center
- University of Washington Medical Center
- Utah State Office of Emergency Management
- Washington Department of Health

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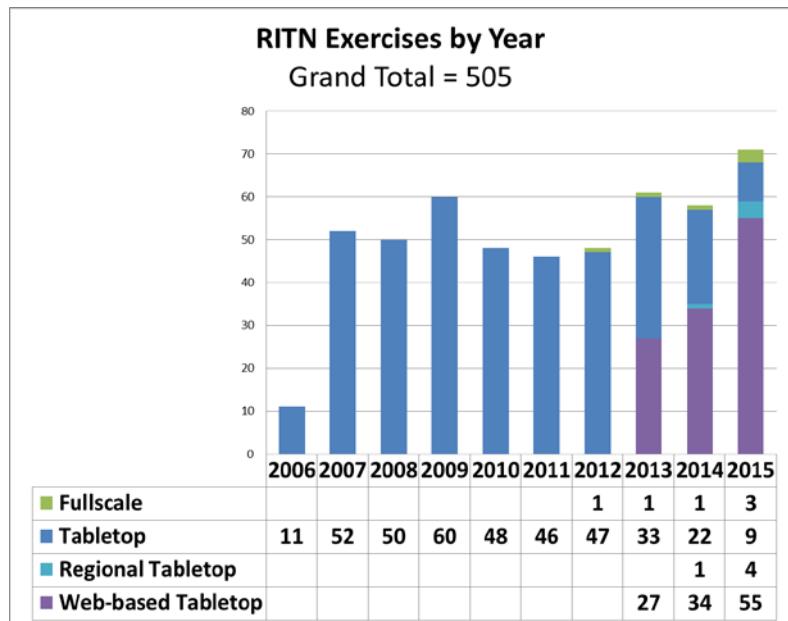


Figure 4. Number of RITN centers participating in exercises from 2006-2015.

Tabletop exercises: The 2015 tabletop exercise presented a scenario where multiple Radiological Exposure Devices were deployed on a university campus with sites required to discuss plans for casualty triage and care. For the second year a facilitated webinar based tabletop was offered to RITN hospitals and was again very well received. The After Action Report for the July 22, 2015 is available [online](#). The number of RITN centers participating in tabletop exercises annually is summarized in Figure 4. A summary of RITN tabletop exercises conducted to date is provided in Table 1.

Table 1. Summary of annual RITN tabletop exercise scenarios and level of patient surge.

Summary of RITN Tabletop Exercise Scenarios		
Year	Scenario	Max Victims
2006	Radiological Exposure Device (RED) placed on public train system	650 identified as having some level of ARS. 50 patients to each center
2007	Train derailment spills multiple chemicals, produces vapor cloud which exposes a crowd of 15,000	5,000 (mostly children and senior citizens)
2008	IND was detonated and 300,000 victims were triaged	5,000 victims required RITN assistance
2009	10-kiloton nuclear device detonated in a major metropolitan center	12,000 patients with high radiation dose in the 200-600

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		rad range. 300 patients to each center
2010	Detonation of a surface burst 10-kiloton nuclear device in major metropolitan center	20,000 patients with high radiation dose in the 200-600 rad range. 500 patients to each center
2011	National Disaster Medical System (NDMS) flow and integration	Not specified
2012	1 KT IND detonated 500 miles away from RITN center, 20 patients to prioritize using provided casualty cards	20 casualty cards w/ limited bed availability provided
2013 w/ Webinar Option	Radiological exposure devices placed on mass transit vehicles in multiple US cities	4,500 casualties nationwide; 300 patients and 140 family members are sent to each RITN center
2014 Primarily Webinar	Detonation of a 1KT IND	100 patients from a large metropolitan area 500 miles away
2015	Four Radiological Exposure Devices (RED) planted on a university campus	20 adult and 20 pediatric patients with detailed patient profiles and required medical evaluation

RITN Sponsored Regional Tabletop Exercises:

During the performance period, two regional tabletop exercise were completed. Regional tabletop exercises were developed by RITN to fill a gap in planning efforts. Communities prepare for disasters that effect their community or their region; but none we have worked with had considered the surge of casualties from a distant radiological incident. We brought together leaders in public health, emergency management, law enforcement, healthcare, federal agencies and non-governmental agencies that support disaster response. Then we presented a scenario where a radiological disaster occurred more than 1,000 miles away; and asked how they would prepare to receive a surge of medical casualties in 7-10 days (per the RITN concept of operations). The after action reports from the [Salt Lake City](#) and [Seattle](#) regional table top exercises are posted on the RITN Web site.

RITN Sponsored Full-Scale and Functional Exercises:

During the performance period, three full scale exercises were sponsored by RITN; these were held at [University of Colorado](#), [University of West Virginia](#), and [Wake Forest University](#). All after action reports are posted on the RITN Web site. Each year RITN solicits hospitals from RITN to submit proposals to conduct full-scale or functional exercises. A full scale exercise is

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significantly larger in scope than a functional exercise. Functional exercises test one specific area such as public communications, emergency operations center activation or patient tracking. Full scale exercises include all aspects of the response. Those given awards receive funding to help conduct the exercise; in exchange for the funding RITN receives copies of all materials which are posted online to help other organizations plan for and conduct their own radiological disaster exercises. For the University of Colorado exercise 11 critical improvement items were documented to be corrected to improve preparedness; ranging from improving patient tracking interface between the hospitals and the National Disaster Medical System, incorporating communications into future exercises, improving utilization of Epic electronic medical records system in the response, updating plan for casualty reception by bus, to improving the contents of the disaster cache.

Training tasks: Then RITN Control Cell defines training to include events that will increase the awareness of RITN and its efforts to the appropriate response community. Training options continue to be accessible online at no cost to anyone who is interested. In addition, the in person training option has expanded to include an Advanced HAZMAT Life Support (AHLs) for Radiological Incidents course. As shown in Figure 11 the training options continue to grow, centers can now choose between conducting Basic Radiation Training, having a physician or Advanced Practitioner complete the REAC/TS training, hosting an AHLs course, conducting an Acute Radiation Syndrome Medical Grand rounds session, and having a site assessment conducted. In addition, centers can conduct community outreach and education using the RITN Overview Presentation. All of these materials, with the exception of the REAC/TS training, are available unrestricted, through the RITN website. The RITN web based training catalog includes:

1. Introduction to RITN
2. RITN Concept of Operations
3. GETS 101
4. Satellite telephone 101
5. Basic Radiation Training
6. Non-medical Radiation Awareness Training
7. Radiation Safety Communication Course

The online learning management system allows RITN center staff to complete the full course at their own pace and receive an electronic certificate of completion after meeting all the course objectives and knowledge assessments. Since 2006, RITN has had a hand in the disaster response training or education of over 12,600 medical staff affiliated with RITN hospitals (Figure 5).

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This year RITN was approached by the National Nuclear Security Administration (NNSA), part of the Department of Energy, to utilize the Non-Medical Radiation Awareness Training for all United States Agency for International Development (USAID) staff worldwide. NNSA will modify the training to remove the portion specific to RITN and plans to use the rest to train workers on the basics of radiation.

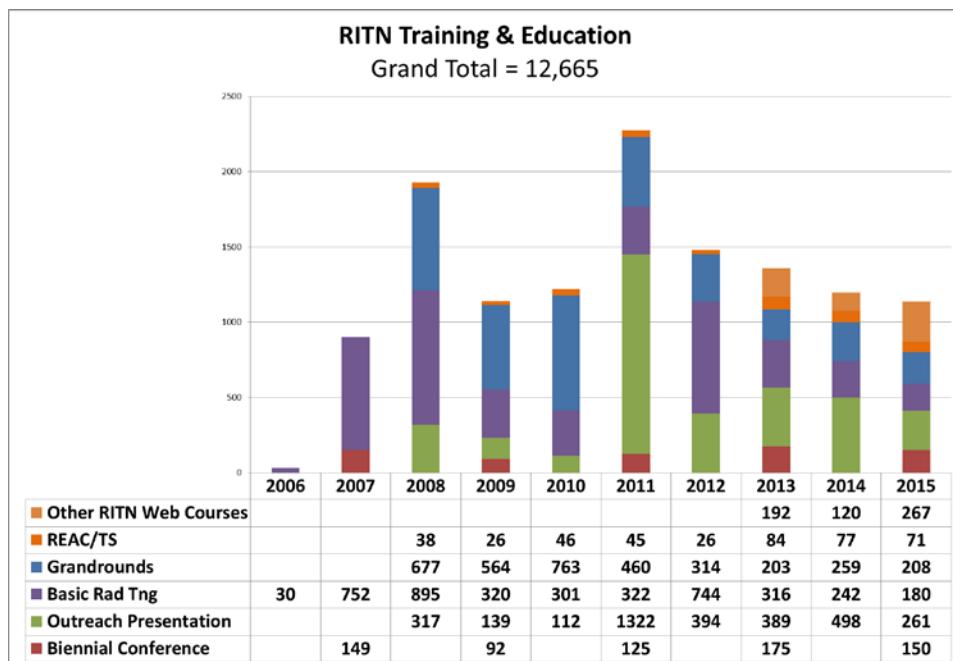


Figure 5. RITN center staff training accomplished by year.

In 2011, RITN initiated the Site Assessment program. RITN Control Cell staff members review existing documentation at RITN transplant centers using a standardized checklist (Figure 6) to assess overall preparedness. Areas evaluated include Casualty Processing, Outpatient Treatment of Casualties, Inpatient Treatment of Casualties, Coordination with City, State and Regional Assets, and Documentation.

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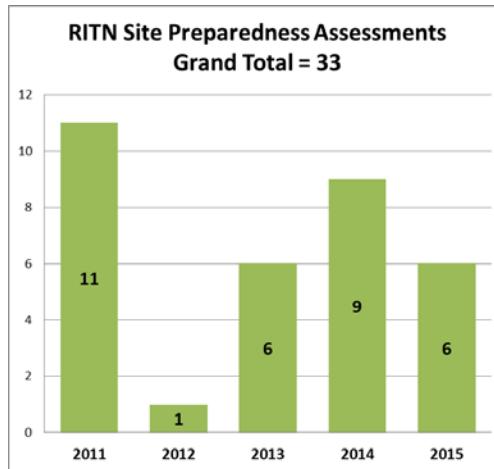


Figure 6. RITN center site assessments by year.

The Site Assessment Checklist formed the basis for revisions to the standard operating procedure (SOP) template that all centers used to update their local SOPs.

The RITN continuously seeks to formalize and develop further partnerships with federal agencies and organizations.

Memoranda of Understanding (MOU) have been established with the following groups to collaborate on preparedness efforts:

- ASBMT since 2006
- Department of Health and Human Services – Office of the Assistant Secretary for Preparedness and Response (HHS-ASPR) since 2007
- AABB-Disasters Task Force since 2008
- New England Center for Emergency Preparedness (NECEP) since 2010
- European Group for Blood and Marrow Transplantation - Nuclear Accident Committee (EBMT-NAC) since 2011

Additionally, the RITN maintains informal relationships to increase awareness about RITN worldwide through close interaction with:

- Biomedical Advanced Research and Development Authority (BARDA)
- Health Resources and Services Administration (HRSA)
- World Health Organization - Radiation Emergency Medical Preparedness and Assistance Network (WHO-REMPAN)
- Radiation Emergency Assistance Center and Training Site (REAC/TS)

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- Armed Forces Radiobiology Research Institute (AFRRI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institutes of Health (NIH) - National Library of Medicine (NLM) - Radiation Emergency Medical Management (REMM)
- American Hospital Association (AHA)
- American Burn Association (ABA)
- Association of State and Territorial Health Officials (ASTHO)
- National Association of City and County Health Officials (NACCHO)
- Veteran's Administration Health System
- Centers for Medical Countermeasures Against Radiation (CMCR)
- National Security Council staff
- National Alliance for Radiation Readiness (NARR)



RITN has received at no cost, access to Health Care Standard® (HCS®) software through a partnership with the developer Global Emergency Resources since 2011; beginning in the next grant period RITN will have to pay for software services and hosting of HCS. This software allows the RITN to consolidate participating hospitals Capability Reports and to communicate situation status updates to the network through a web based interface. Annual tests are conducted to ensure that users are familiar with the system and that it is capable of receiving and consolidating submitted data. This system allowed RITN to collect the bed availability and on-hand G-CSF quantities throughout the network during a prior grant period.



The Assistant Secretary for Preparedness and Response from the Department of Health and Human Services has been a partner since the foundation of RITN. This partnership is formalized through an MOU and is prominently displayed on the Department of Health and Human Services website for Public Health Emergencies on the Chemical, Biological, Radiological, Nuclear and Explosive Branch page, (<http://www.PHE.gov/about/oem/cbrne>, and Figure 7):

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The screenshot shows the CBRNE Branch page of the U.S. Department of Health & Human Services website. The page features a navigation bar with links to Preparedness, Emergency, About ASPR, and the Office of the Assistant Secretary for Preparedness and Response. Below the navigation is a banner for Public Health Emergency: Public Health and Medical Emergency Support for a Nation Prepared. The main content area is titled "CBRNE Branch". It includes a section on Partnerships and Projects, listing four resources: CHEMM (Chemical Hazards Emergency Medical Management), REMM (Radiation Emergency Medical Management), State & Local Planners Playbook for Medical Response to a Nuclear Detonation, and RITN (Radiation Injury Treatment Network). A sidebar on the right is titled "CBRNE" and contains links to "About CBRNE", "Additional Resources" (including CBRNE Training Resources, Chemical, Biological, Radiation/Nuclear, Explosives, CDC Learning Connection, and REACTS), "Other CBRNE Resources" (Disaster Medicine and Public Health Preparedness, Planning Guidance for a Response to a Nuclear Detonation, Radiological Dispersal Device Playbook), and "Get the Mobile Apps" with a QR code.

Figure 7. Chemical, Biological, Radiological, Nuclear and Explosive Branch webpage noting the partnership with RITN.

NMDP's critical functions must remain operational during contingency situations that directly affect the Coordinating Center.

Operational Continuity Planning (OCP) is essential for world-class organizations to meet the myriad of 21st century emergencies; this is evident by the visibility of many standards, such as ISO 22301:2012 which specifies requirements to plan, establish, implement, operate, monitor, review, maintain and continually improve a documented management system to protect against, reduce the likelihood of occurrence, prepare for, respond to, and recover from disruptive incidents when they arise. The OCP is comprised of plans, systems, and processes for resuming NMDP operations in the shortest time possible following a severe operational disruption. OCP focuses on increasing the resiliency of the staff essential to conduct recovery operations, the

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facilities required to house these staff members, and the specialized long lead time equipment needed to connect these staff members to our data center from remote locations.

The OCP mitigates the effect of the many incident categories that may adversely impact NMDP operations. The OCP does not specifically plan for each possible hazard to the organization, rather it has a broad scope with a flexible and scalable response to allow for a successful activation in response to various catastrophic events ranging from fires, flooding, pandemics, extended evacuations (due to building damage, local chemical spill, or other hazards making the facilities unusable), to extended service outages such as water, electricity or sewer services. The OCP does not include NMDP Data Center incidents, as these are covered by the Information Services department through the Disaster Recovery program. NMDP continues to annually test its OCP to validate functionality with the continually changing information system environment as well as the growing organization structure and operational complexity.

The NMDP requires specialized technical staff to accomplish the organization's mission. The technical skill sets required are not readily replaceable. Without these staff members, the NMDP would not be able to support its network of centers in their daily operations and research programs. The NMDP OCP outlines procedures to allow resumption of operations within 72 hours of a catastrophic disruption. This is essential for the HCT community that relies on NMDP staff and systems for timely access to critical graft sources.

Other OCP support activities included an update of the NMDP plans to meet the requirements specified in [ISO standard 22301:2012](#) (Societal security -- Business continuity management systems). The emergency communications system components (satellite telephones, GETS cards, and the mass telephonic alert system) were maintained and tested. The Operational Continuity Steering Committee reviewed changes and additions to the Critical Task List at their annual meeting. The committee is co-chaired by the Chief Medical Officer and the Strategic Development Officer and seated by the Chief Information Officer; Chief Financial Officer; Chief Legal Officer; and the Chief Operating Officer.

Development of Science and Technology for Rapid Identification of Matched Donors

Increasing the resolution and quality of the HLA testing of volunteers on the Registry will speed donor selection.

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In NMDP FY15 (Oct. 2014-Sept. 2015), NMDP donor centers (including Department of Defense (DoD)) and recruitment groups recruited 184,188 minority race and 181,054 Caucasian donors, for a total of 365,242 U.S. donors added to the registry. Navy funding supported the HLA typing of 110,663 donors (excluding DoD) of this culturally diverse group (50% minority).

Advancing technology improved performance and pricing

The NMDP typing strategy maximizes the use of funds by utilizing new typing methodologies that deliver a higher resolution of results at a lower cost than previous methods. The overall goal is to ensure that new donors are listed on the registry with the best possible resolution and number of loci tested. This is particularly critical during times of a contingency where well HLA-characterized adult donors must be readily matched to patients in need of HCT for ARS.

- Since April 2014, all new donors are typed at minimum of HLA-A, B, C, DRB1, DQB1, and DPB1.
- Since April 2015, all donors are typed by an exon-based NGS approach that delivers G-group resolution or better.
- Through a Request for Proposal process that is currently ongoing, NMDP expects to realize additional economic savings while increasing resolution to full gene Class I and long range Class II sequencing.

Sample Storage Research Study

Table 2: Results for the buccal swab stability study

4 Year Time Point – 2011	5 Year Time Point – 2012
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HLA Typing: <ul style="list-style-type: none">• 100% accuracy for whole blood• 100% accuracy for filter paper• 100% accuracy for buccal swabs	HLA Typing: <ul style="list-style-type: none">• 100% accuracy for whole blood• 99% accuracy for filter paper• 97% accuracy for buccal swabs
DNA Quantity: Sufficient for testing	DNA Quantity: Sufficient for testing
DNA Quality: Buccal swab DNA showing degradation <ul style="list-style-type: none">• 5 swabs (17%) needed repeat testing	DNA Quality: Filter paper samples showing degradation, Buccal swab DNA showing more degradation than in 2011 <ul style="list-style-type: none">• 14 filter papers (47%) and 24 swabs (80%) needed repeat testing

Results show that DNA degradation issues first seen in Year 4 increased in Year 5, with buccal swabs showing degradation earlier than blood spotted onto filter paper (Table 2). The study was presented at the November 2013 annual meeting of the American Society of Histocompatibility and Immunogenetics (ASHI), and was recognized with the award for ‘Best Stem Cell Case Study’¹. The study prompted re-evaluation of the NMDP Repository storage model and led to the development of the frozen swab storage strategy that was implemented in 2015. A manuscript is currently being drafted to report the study results and is targeted for submission in FY17.

DNA storage methods transition to frozen buccal swab model

Be The Match Registry member samples stored at the Biorepository provide the basis for Customized Typing requested on behalf of patients allowing for rapid testing in the event of a national disaster, and for prospective registry upgrade typing. The transition from controlled room temperature storage to frozen storage at -30°C has been designed to preserve the long-term utility of the remaining buccal swabs collected at time of recruitment.

Baseline time point samples, both at controlled room temperature and short-term frozen (-30°C), and samples stored for 1 year at room temperature and frozen (-30°C) have been tested at two labs for DNA quantity and quality, and typing at HLA-A, B, C, DRB1, DQB1, DPB1 by 3 methods:

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- High resolution SBT (sequence-based typing) with Sanger methodology
- High resolution SBT with long range NGS (next generation sequencing) methodology
- Intermediate resolution with SSO (sequence specific oligonucleotide) methodology.

Baseline results indicate similar DNA quantity and quality from both frozen and room temperature swabs, and HLA concordance with SBT and SSO HLA typing methodologies. However, with the long range NGS methodology, there were a few discrepancies and some amplification failures observed with the frozen samples (rate of 3.74%) that were not observed with the room temperature cohort. This elevated rate of problematic loci for the frozen samples could be inherent to the longer amplicons being tested, which may be more fragile after a freeze/thaw cycle. Therefore additional baseline samples were shipped in a frozen state to retain their integrity until the lab began testing the samples, as opposed to the samples undergoing a thaw cycle during ambient shipping conditions en route to the lab. While analysis of the additional samples indicate continued problems for amplifying Class II loci with the long range NGS approach, the problems are equally present for both the controlled room temperature as well as the frozen-shipped-frozen swabs.

For the one year time point of the study, the samples that were stored frozen were shipped to the typing laboratories on dry ice to preserve their frozen state until the lab was ready to extract the DNA and amplify. The one year time point results had similar DNA quantity and quality from both frozen and room temperature swabs, as well as 100% HLA concordance with SBT, SSO, and long range NGS HLA typing methodologies for samples from both storage conditions. There were a few DNA amplification issues with the SSO methodology that were present for both frozen (rate of 6.7%) and room temperature control (rate of 6.7%) samples. Likewise, there were also DNA amplification issues with the long range NGS methodology for both frozen (rate of 10.0%) and room temperature control (rate of 6.7%) samples.

The long range NGS methodology has encountered problems throughout the various time points with both the frozen and room temperature controls. The problems with NGS consisted of a few discrepant results at the baseline time point, and several amplification failures at both a sample level and at a locus level. Since the problems with the long range NGS approach have occurred with both the frozen and the room temperature control samples (although at a slightly elevated rate with the frozen cohort), this could be more of a consequence of the limitations of this emerging technology with reagents and techniques not yet optimized. The next time point of the frozen swab study will be at 3 years of storage.

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Enhancing Non-HLA data for selected donors

Transplant centers utilize donor cytomegalovirus (CMV) status and blood type (ABO/Rh) as non-HLA selection factors when multiple equally well matched donors are available. Currently the only process to obtain this information is to request the potential donor on behalf of the patient, obtain a fresh blood sample, and perform IDM tests that include the donor blood type and presence/absence of circulating antibodies to CMV.

CMV at Recruitment by DNA-based testing

Real-time PCR testing for CMV DNA was performed in a pilot study using recruitment buccal swab samples from 500 donors. Known CMV seropositive and seronegative samples were identified from Confirmatory Testing subsequent to recruitment (234 seropositive, 266 seronegative). The study yielded results with an assay sensitivity of only 2.1%, a specificity of 99.6%, a positive predictive value of 83.3%, and a negative predictive value of 53.6%. An adjusted calculation was made to adjust for the fact that only about 15% of CMV seropositive donors would be actively shedding the virus to saliva. Adjusted for the rate of CMV shedding the sensitivity rate remains low at 14.3%. This low sensitivity rate does not allow for effective identification of CMV positive donors.

ABO/Rh at Recruitment by DNA-based testing

Due to recent advances in testing methodology (primarily due to NGS), it became feasible to explore adding ABO/RhD as another locus that could be tested from the same sample at the same time as recruitment HLA testing. The NMDP made sets of 1000 blind samples available to two laboratories for validation testing. A high degree of concordance between genetic ABO/RhD result and known serological ABO/Rh was seen for both sets (>97% concordance). DNA-based ABO/RhD testing on a portion of recruitment samples began in August, 2014. As of October 01, 2014, all recruitment samples receive ABO/RhD testing along with HLA testing.

Quality of HLA typings improved

The NMDP's comprehensive quality control program has supported the successful increase in the quality of HLA typing received through the contract laboratory network. Blind Quality Control (QC) samples are added to each weekly shipment of new donor recruitment samples.

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These QC samples comprise 2.5% of each shipment and are indistinguishable from the other samples. With the help of this grant, there are more than 700 QC Masters in active rotation, representing over 95% of common well-documented (CWD) HLA alleles. In order to maintain a robust and diverse inventory of QC Master samples into the long term future, a program to obtain samples from Registry donors with desirable HLA types and other unique immunogenetic factors is being developed.

Cord Blood Unit QC sample collection

NMDP has actively engaged network cord blood banks to acquire units that are not deemed suitable for banking in an effort to increase the diversity of cord blood material for the cord QC program. In the last grant period, NMDP purchased 35 such cord blood units. A sample from each unit was typed at high resolution by NGS for Class I and II HLA genes, and the remaining material was aliquoted and stored frozen at the Biorepository. The aliquots will be included on QC test panels for NMDP's contracted cord blood unit confirmatory typing laboratory and may also be used to further monitor the NMDP contract laboratory performing immunogenetic testing on cord blood units at the time of recruitment.

Additional Projects to Ensure Quality of HLA Data

Following the success of the review of rare allele typing and the identification of alleles which were incorrectly typed, this project has moved to the evaluation of uncommon alleles reported in the Be The Match Registry through primary data interpretation. Review of HLA results of non-CWD and uncommon alleles reported to the NMDP on adult volunteer samples revealed typings that were suspicious and may have been incorrectly reported due to various reasons including:

- Typing methodologies used to report the allele were problematic
- Allele reporting of the allele in question were more prevalent prior to 2006
- Presence of two less common alleles in a donor typing
- Primary data interpretation does not support the reported typing
- Allele reported in a race/ethnic group different from the reference cell in the IMGT/HLA database

Samples were identified using the above rules and retyped by SSOP technology. A total of 1421 samples were typed through the project in the last grant period.

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Table 3 shows the results of the retying of 1421 non-CWD or uncommon reported allele calls many of which initially had supporting primary data. The low confirmation rate demonstrates that the primary data reporting had inaccurate results for the actual rare/uncommon allele calls.

Table 3. Results of the re-typing of 1421 non-CWD allelic results reported to the Registry.

	# typed	corrected	% corrected
HLA-A	185	128	69%
HLA-B	291	143	49%
HLA-C	8	8	100%
DRB1	898	346	39%
DRB3/5	365	217	59%
DQB1	33	25	76%

These incorrect data were revised on the registry and will now appear correctly on searches. In addition, the data obtained in these retying projects allows for more accurate interpretation of the EM algorithm when evaluating haplotypes. These projects also identify problematic alleles that become candidates for inclusion within the NMDP QC program.

Proactive Information Session Phase 1

Research suggests that stem cell transplantation that performed in the early disease stage results in more successful patient outcomes ^{2,3}. However, time to transplant for a patient can be delayed

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due to waiting for confirmation of donor availability, completion of donor HLA typing, and evaluation of non-HLA factors, such as age, ABO, and CMV status. The aim of this project is to provide transplant centers with a pool of pre-screened, fully-matched donors that are able to go immediately to workup if a patient's search is urgent, and which are optimized for the patient's non-HLA factors. Prospective donors were contacted to confirm availability, underwent additional testing to upgrade non-HLA information, and were given a proactive information session to further educate and prepare them should they be asked to donate for a patient.

Ninety patients from U. S. transplant centers have been enrolled in this project. To date, 39% of those cases that received donor recommendations from the pre-screened pool subsequently activate one of those donors. Additionally, transplant centers that formalize donors before any recommendations can be provided are identifying these pre-screened donors themselves.

Overall, 36 of 105 donors that have completed this process have been requested for confirmatory typing with some donors activated for multiple patients. To date, 13 enrolled donors have been selected for workup, and 5 have proceeded to or are scheduled to donate. Additionally, availability at confirmatory typing (CT) or workup for these enrolled donors was 85%, compared to 50% availability for similar donors that did not complete this process. Upgrading the availability, HLA, and non-HLA information displayed to transplant centers allows them to optimize their donor selections, as well as move quickly if a patient's search is urgent. A second phase of this project is scheduled to begin in Summer 2016.

Primary DNA typing data can be used within the Registry to improve the quality and resolution of volunteer donor HLA assignments.

An HLA assignment obtained by SSOP, DNA-based testing methods is derived from the positive and negative hybridizations of oligonucleotide reagents that define the presence of specific nucleotide sequences. Using this information and a list of known HLA alleles with their primary sequences, the typing laboratory interprets the hybridization results into possible allele combinations (interpreted data). The information for which polymorphic nucleotide sequences are present or absent is termed “primary data.” Similar primary data are available from other DNA-based methods, sequence specific primers (SSP) and sequence-based typing (SBT).

Several informatics challenges face the NMDP in regard to DNA-based HLA typing:

- New HLA alleles are described at a rate of approximately five per week.

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- The low/intermediate resolution typing of newly recruited donors is reported as groups of potential alleles within families and assignments become outdated as new alleles are discovered within these families.
- Almost every low/intermediate resolution HLA assignment will be outdated within a single year unless a mechanism is developed to retrospectively incorporate newer alleles into previously reported results.

Searches are difficult for patients who carry new alleles, as matching must consider the donors tested before the new alleles were described.

Because the low/intermediate resolution of the HLA typing usually includes strings of possible alleles, the laboratory must condense down the assignments into single reportable combinations that separate the possibilities for each chromosome at that locus. For example, A*02:01/02:02 and A*03:02/03:03 will be reported in the condensed format A*02:AB, 03:BC. Through this reporting process, new allele genotypes are implied which did not exist when the two chromosomes were actually tested together.

Example:

1st chromosome	2nd chromosome	
A*02:01	A*03:03	Actual genotype pair 1
A*02:02	A*03:02	Actual genotype pair 2
A*02:01	A*03:02	Did not exist
A*02:02	A*03:03	Did not exist

In this example, A*02:01, 03:03 or A*02:02, 03:02 were the actual interpreted possible types for a donor. The condensation into codes creates the additional potential types of A*02:01, 03:02 and A*02:02, 03:03 which did not exist at the time the laboratory performed the testing. This situation is termed “phase mismatching.” To further complicate the search process, due to the low/intermediate resolution donor typing, a patient with a less common allele might appear to have many potential donors, but the majority of these donors will not carry the patient’s assignment when tested at a higher level of resolution.

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HLA typings based on nomenclature become outdated and diminish in value over time. This objective sets a new standard for managing HLA data by developing standards, methods, data formats and tools that allow the raw DNA information to be used.

Histo-immunogenetic Markup Language Gateway

We have implemented a new “HML Gateway” which increases our data processing capabilities utilizing cloud-based computing, and enhances the stability and security of information transmitted to the registry. The HML message format allows for the acquisition of genetic data that will be used for matching donors and recipients typed by Next Generation Sequencing technologies. Transplant Centers and other network partners depend upon the data accepted by the HML Gateway system for this purpose and will benefit by higher resolution and additional gene families.

MAC and FHIR HL7 Terminology Service

HL7 FHIR makes extensive use of defined vocabularies and terminologies to ensure structured reporting as unambiguous as possible. These include Code Systems and Value Sets, and Terminology Services to support these (see <https://hl7.org/fhir/terminology-service.html>). To use FHIR resources effectively, FHIR terminology services for histoinmunogenetics need to be developed. For example, a HL7 FHIR Terminology Service API has been developed for a set of code systems that could potentially be used by the NMDP for nomenclature-level HLA data. This service has been implemented as an API gateway to the Multiple-Allele Code (MAC) service.

The service operates mainly on three HLA code systems, labeled here as hla-multiple-allele-code, hla-amino-acid-allele, and hla-genomic-allele. Conceptually, the three code systems are non-overlapping: hla-multiple-allele-code includes only multiple-allele codes, hla-amino-acid-allele includes only 2-field short allele names and short names where an expression suffix has been transposed, and hla-genomic-allele includes only full-length IMGT/HLA genomic allele names. While it is possible for seemingly equivalent codes to be defined in both the hla-amino-acid-allele and hla-genomic-allele code systems, the exact meaning of such a code may differ depending on which code system (and version) defines it.

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Source code for the prototype "MAC and FHIR" terminology service is on Github:

<https://github.com/nmdp-bioinformatics/multiple-allele-code>

Focusing on deeper work in HL7 FHIR for Clinical Genomics

FHIR's fundamental core element is the Resource. These are limited in number and represent the core elements to be used in at least 80% of FHIR implementations in healthcare systems. At this time, there are 93 resources in the Draft Standard for Trial Use (DSTU) 2.0 FHIR specification, and 11 more for a total of 104 resources in the current build that is preparing for the next DSTU ballot. These resources include objects such as Patient, Observation, Encounter, Medication, etc. In order to achieve 100% usefulness, the remaining 20% is expressed in Profiles containing Extensions that represent special use cases. Last year, the HL7 Clinical Genomics Work Group introduced a FHIR Profile of the Observation Resource representing Genetic Observation that included key data elements for nucleic acid and protein sequences and associated metadata. Early testing of this Profile revealed significant limitations in applying this to several use cases. It became evident that fundamental to each use case was the concept of Sequence and it would be reused in different Profiles for clinical genomics. This resulted in the development of a new Sequence Resource that was introduced into the current build in Oct 2015. Along with this new resource, new Profiles were developed to explore specific use cases. These other Profiles are summarized in Table 4.

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Table 4. HL7 FHIR Resources and associated Profiles

FHIR Resource	Profile
Observation	Genetics ObservationForGenetics Consensus-sequence-block
Diagnostic Report	ReportForGenetics HLAResult
Diagnostic Order	OrderForGenetics
FamilyMemberHistory	FamilyMemberHistory-Genetic
Sequence (new)	None yet

Two of these Profiles (HLAResult and Consensus-sequence-block) were developed for the HLA genotyping report use case and was informed by MIRING and HML 1.0. While the development of this Sequence Resource and new Profiles is exciting, it is by no means complete. In particular, although these HLA related Profiles capture many of the elements and metadata in HML 1.0, they are not complete and there are significant issues that remain in their design. We are working with the Clinical Genomics Work Group to model different HML 1.0 reports using the current specification and suggesting changes that will modify the format to better fit HLA. The HL7 Clinical Genomics Working Group continues to develop and test the FHIR specifications with new resources and profiles will undoubtedly be introduced this year.

In the past year we developed the HLA 1.0 data standard and the HML Gateway, a cloud based message processing pipeline for validating HML 1.0 messages. The focus of this aim in the next year is on development of a system for downstream storage and analysis of genomic data.

NGS technologies have brought about a shift in the focus of HLA testing from targeted sequencing of 1 or 2 exons to methods that target the full genes – in some cases spanning between untranslated regions (UTRs). As of IMGT/HLA Release 3.24.0, less than 7% of the named classical HLA alleles have curated full-length gene sequences or sequences outside the antigen recognition domain (ARD).

Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor or cord blood unit.

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HLA allele and haplotype frequencies are central to matching and the selection process as well as for more strategic tasks such as modeling registry growth or estimating match rates beyond the typing resolution of the donors in the registry. This objective contains a number of specific tasks that build on other objectives (such as IIB.2) and inform other research aims such as (IIC) Immunogenetics studies.

Manuscripts

- Besse K, Maiers M, Confer D, et al. On Modeling Human Leukocyte Antigen-Identical Sibling Match Probability for Allogeneic Hematopoietic Cell Transplantation: Estimating the Need for an Unrelated Donor Source. *Biol Blood Marrow Transplant.* 2015 Sep 25. pii: S1083-8791(15)00618-7. doi: 10.1016/j.bbmt.2015.09.012.
- Single RM, Strayer N, Thomson G, et al Asymmetric linkage disequilibrium: Tools for assessing multiallelic LD. *Hum Immunol.* 2015 Sep 7. pii: S0198-8859(15)00438-3. doi: 10.1016/j.humimm.2015.09.001.

Conference Presentations

ASHI, September 28 – October 2, 2015, Savannah, GA

- Paunić V, Gragert L, Schneider J, et al. Evaluation of HLA typing ambiguity in the US registry.

Individualizing Medicine 2015, September 20 - 23, 2015, Rochester, Minnesota

- Milius B. Resources to Support Genomic Medicine.

HLA-DP matching service

We implemented an open-source (<https://github.com/nmdp-bioinformatics/service-epitope>) REST microservice that assigns TCE group to HLA-DPB1 alleles and computes TCE-based permissibility categories for a given patient/donor pair. This service has been operationalized and is now used regularly by Transplant Centers via the Traxis user interface and HapLogic matching algorithm.

9-locus haplotype frequencies and HLA-DP prediction

Extension of recruitment HLA typing to additional loci in recent years has allowed us to complete an analysis of 9-locus A~C~B~DRB3/4/5~DRB1~DQA1~DQB1~DPA1~DPB1 haplotype frequencies. This data is being prepared for publication. We have also developed a system to use this data to predict DPB1 matching as defined by T-Cell epitope reactivity (TCE)

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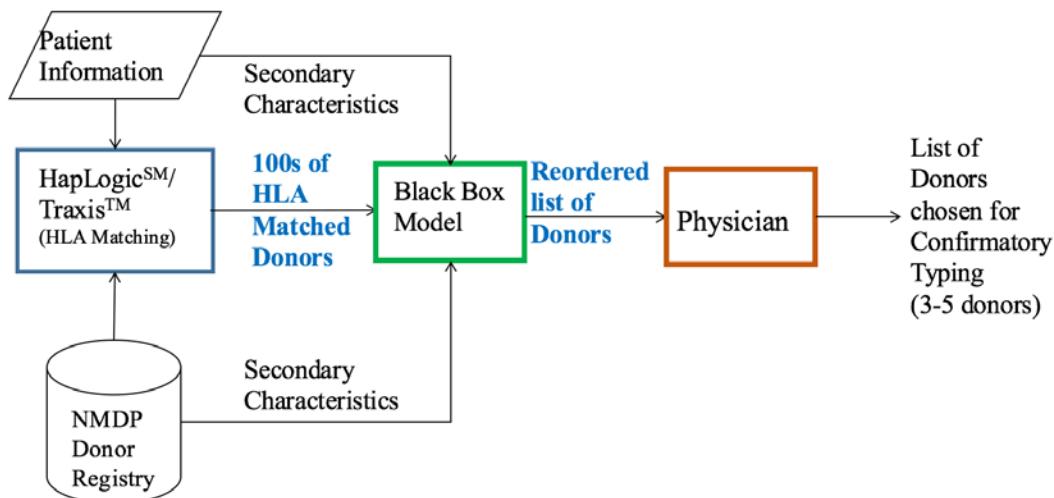
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groups^{4,5,6} and more recently in terms of non-permissive DPB1 mismatch based on DPB1 expression variants⁷. We compared the predicted TCE and expression permissibility for each pair to their true TCE and expression permissibility using the receiver operator characteristic (ROC). The ROC area under the curve (AUC) was greater than 0.90 for most populations. The average AUC observed was 0.92 with a standard deviation of 0.02 between populations. Imputation of DPB1 permissibility can be performed with strong predictive power for every major population when using A~C~B~DRB1~DQB1~DPB1 haplotype frequencies.

In the past year we published results of a study applying the machine learning method of “Cost-Sensitive Support Vector Machine (SVM)” to Donor Selection for Hematopoietic Stem Cell (Figure 8). This system used a historical archive of searches with the full lists and attributes of donors to train a model to learn how secondary variables (non-HLA) are used to prioritize donor selection. The results of the experiments was a better ranking that sorted the selected donors higher in a validation cohort. The goal of the model is a ranking system that can be applied in real-time to searches to assist the donor selection process, highlight best practices and avoid mistakes.



Objective is to help human physicians by suggesting most suitable donors based on historical choices

Figure 8. Schematic for automated donor selection process

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Search Prognosis - Genotype Frequency Study

The goal of this project was to develop a simple scoring system that uses a patient's genotype frequency to determine whether the patient is likely to have a 10/10 donor (good search), a 9/10 donor (fair search), or neither (poor search). The genotype frequency boundaries for the three prognosis categories were defined in each of the four broad race groups - African American (AFA), Hispanic (HIS), White (WH), and Asian/Pacific Islander (API) - and an unknown race group (UNK) using a proportional odds model on a training data set of over 2400 patients.

A validation analysis was conducted to assess the precision of using genotype frequency to predict search prognosis. A second cohort (n= 2411) was used to calculate the concordance for each race group in all three categories: Good: WH: 94%, AFA: 58%, API: 89%, HIS: 74%, and UNK: 83%; Fair: WH: 61%, AFA: 91%, API: 72%, HIS: 84%, and UNK: 71%; and Poor: WH: 83%, AFA: 44%, API: 61%, HIS: 44%, and UNK: 70%. Additionally, a validation was performed against an independent cohort previously resolved as having a 10/10, 9/10, or no such matched donor, which demonstrated the genotype frequency categories defined here provide differential likelihood of donor matching. A prototype online tool that can output a search prognosis (good, fair, or poor) by simply entering a patient's HLA has also been developed. This manuscript was published in Bone Marrow Transplantation⁸

Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

DPB1 TCE Donor Selection Study

Recent research suggests that beyond 8/8 allele level matching at HLA-A, B, C, DRB1, matching at HLA-DPB1 TCE should be considered to improve patient survival rates in allogeneic stem cell transplantation. Non-permissive TCE mismatches at DPB1 appear to associate with a higher incidence of transplant related mortality in patients that have a 10/10 matched donor. The aim of the project was to identify the DPB1 TCE match rates of patients with 10/10 URD in the Be The Match Registry as well as understand how much prospective donor testing is required to optimize DPB1 matching.

Patient enrollment has been closed with 595 patients from 33 domestic transplant centers. 801 donors have been typed at DPB1 on behalf of these patient searches. Patient T cell epitope group

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(TCE) was determined utilizing the latest TCE allele classification from the Crivello, *et. al.*, 2015 paper⁹

Table 5. Results of the DPB1 TCE Donor Selection Study

	Pre Typing TCE Match (% of Total)	Post-Typing TCE Match (% of Total)	Total
Group 1	20 (44%)	25 (56%)	45
Group 2	92 (62%)	106 (72%)	148
Group 3	299 (74%)	347 (86%)	402
Total	411 (69%)	478 (80%)	595

DPB1 matching rates improved post-typing regardless of TCE group of the patients (table 5). This strategy to identify well matched donors that are either DPB1 allele matched or permissively mismatched did not hinder search progression and was likely for 80% of the patients enrolled in the study. As more donors are added to the registry with DPB1 typing, the pre-typing match rates are likely to improve.

Genotype Frequency Project

The aim of this project was to determine the impact of proactive intervention by the NMDP on searches with poor prognosis as defined by patient genotype frequency. These searches were characterized as having limited donor options, where even finding a 9/10 matched donor may not be possible.

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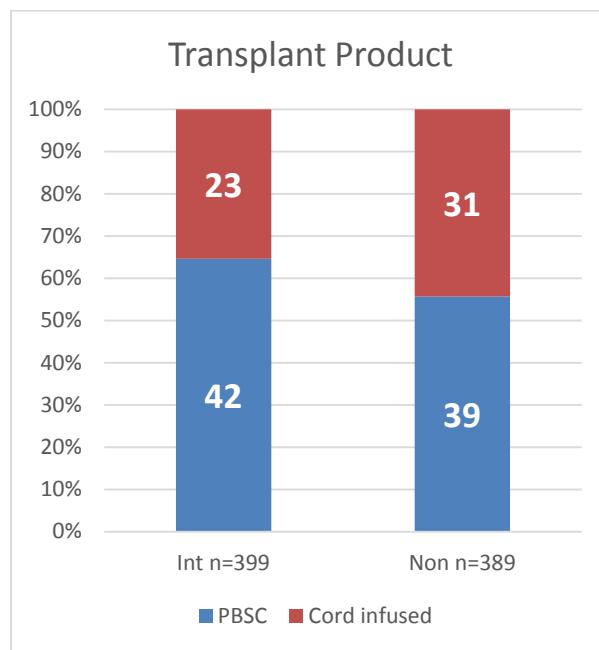
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Between April and October 2015, patients from domestic transplant centers with a search determined to have poor prognosis using the Genotype Frequency Tool were randomized into two groups, intervention (399 patients) and non-intervention (389 patients) for comparative purposes. The project provided proactive donor contact, typing and/or search strategy advice early in the search process for patients enrolled in the intervention group. The goal was to determine if this type of intervention helps cases with limited donor options proceed forward from the preliminary stage, decrease the time to transplant and influence the product (donor or cord blood unit) pursued. Search strategy advice and 9/10 or better donors who were identified were messaged to transplant centers through their respective case managers.

A total of 147 9/10 donors and four 10/10 donors were identified for patients enrolled in the intervention group. Overall patient data show a larger number of younger donors were contacted and/or typed through this project for API and HIS patients, suggesting improved donor typing for these groups could be beneficial. The number of total donor/cord blood transplants between groups was similar (65 intervention and 70 non-intervention), but a greater number of donors were utilized in the intervention group (35% cord) whereas a greater number of cords were utilized in the non-intervention group (44%) (Figure 9). The results of the study will be analyzed and reported under a subsequent grant.



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Figure 9. Product type selected for patients proceeding to transplant in the genotype frequency intervention project.

NIH Search Support

The National Institutes of Health (NIH) has been accepted as an NMDP transplant center since 2007. Prior to that time, the NIH, representing our Nation's premier medical research endeavor, was not applying their considerable problem-solving skills to issues surrounding unrelated donor transplantation. The NMDP, with ONR support, set out to remedy that deficiency by entering into collaboration with NIH. This collaboration has been extremely successful.

The NMDP is collaborating with intramural NIH transplant programs from the National Cancer Institute, the National Heart Lung and Blood Institute and the National Institute of Allergy and Infectious Diseases. These programs are investigating alternative approaches in unrelated donor transplantation to improve patient outcomes. The actual transplants and the investigational portions of each transplant (i.e., the research protocols) are supported entirely with NIH funds. Navy funding supplies support for donor identification, selection and collection. NMDP donors are not research subjects on these protocols because the donors are making standard donations for accepted transplant indications. The research component of these transplants is conducted entirely by NIH intramural program staff and funded entirely with NIH dollars. The NMDP provided support for the collection of 16 products (6 PBSC, 4 CBU and 6 marrow) under this grant.

Rapid identification of potential donors for newly diagnosed AML patients

The Southwest Oncology Group (SWOG) has identified the time from diagnosis of Acute Myelogenous Leukemia (AML) to transplant as critical for successful treatment of patients with cytogenetically defined high risk disease. Proceeding to transplant within four months of diagnosis for patients with high risk disease in first chronic remission could potentially improve the overall disease free survival rates. Currently, these patients are referred for transplant following cytogenetic screening and several lines of therapy. The initial diagnosis and treatment phase can take several months significantly delaying the initiation of an unrelated donor search and making transplant within four months highly unlikely. NMDP/CIBMTR up front involvement would permit the rapid identification and pre-search screening of potential donors, so patients will be well along in the search process when/if ultimately referred for HCT.

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In April 2013 SWOG initiated the clinical trial entitled, [S1203: A Randomized Phase III Study of Standard Cytarabine plus Daunorubicin \(7+3\) Therapy or Idarubicin with High Dose Cytarabine \(IA\) versus IA with Vorinostat \(IA+V\) in Younger Patients with Previously Untreated Acute Myeloid Leukemia \(AML\)](#). The trial is a randomized phase III trial of cytarabine and daunorubicin hydrochloride or idarubicin and cytarabine with or without vorinostat to see how well they work in treating younger patients (18-60 years old) with previously untreated acute myeloid leukemia. Drugs used in chemotherapy, such as cytarabine, daunorubicin hydrochloride, idarubicin, and vorinostat, work in different ways to stop the growth of cancer cells, either by killing the cells or stopping them from dividing. Giving more than one drug (combination chemotherapy) and giving the drugs in different doses and in different combinations may kill more cancer cells. It is not yet known which combination chemotherapy is more effective in treating acute myeloid leukemia. The study includes a transplant arm for patients diagnosed with high risk cytogenetics following the initiation of induction therapy (see Figure 10 below). NMDP/CIBMTR is supporting the project using grant funds to provide study-specific sample collection kits for all enrolled patients, processing samples, HLA typing patients that are diagnosed as cytogenetic high-risk and generating preliminary search strategy reports to assist in the identification of donors and/or CBUs through the NMDP. The resulting search information is provided to the S1203 transplant arm principal investigator who shares the data with the referring physician.

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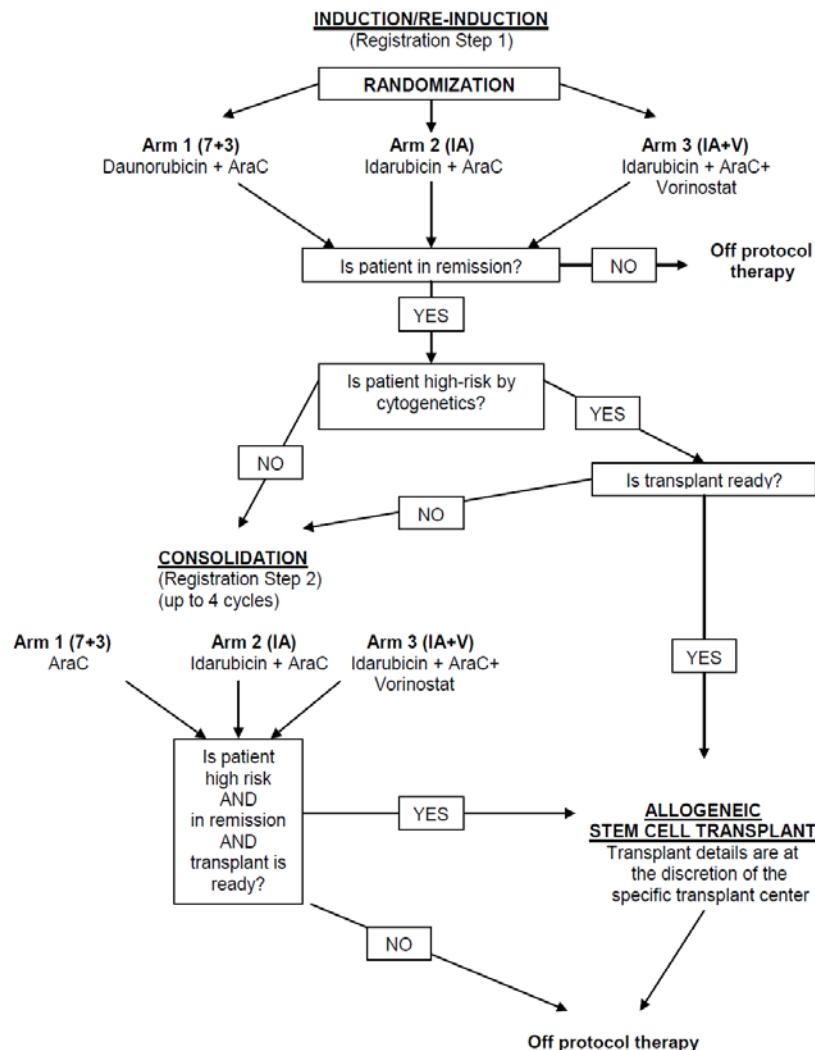


Figure 10. S1203 trial randomization and treatment schema.

The study opened in April 2013 and accrual was completed November 2015.

Activity during the project:

- Accrual dates 4/1/2013 to 11/4/2015
- 752 patients were enrolled in the study

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- 751 sample collection kits distributed to patients
- 694 kits were collected and returned to the repository
- 185 patients were considered high-risk or unknown risk
- 179 patients were HLA typed
 - includes patient's that were downgraded to low/intermediate risk after the sample was shipped for typing
 - 19 patients were not sent for typing (they passed away or were taken off the study)
 - The lab reported 1 no-make, while the sample was at the lab, the patient was removed from the study, so replacement swabs were not requested
- 179 patients had a preliminary search completed

For this study, 25% of this patient population were considered high risk by cytogenetic testing.

Patients that were high risk had their collected swabs shipped to a laboratory for High Resolution HLA-A, B, C, DRB1, & DQB1. The laboratory's contracted turnaround time was 7 calendar days. When the typing was completed, the patients HLA typing and simple demographics (age, sex, race, weight) were sent to the NMDP's Search Strategy Team.

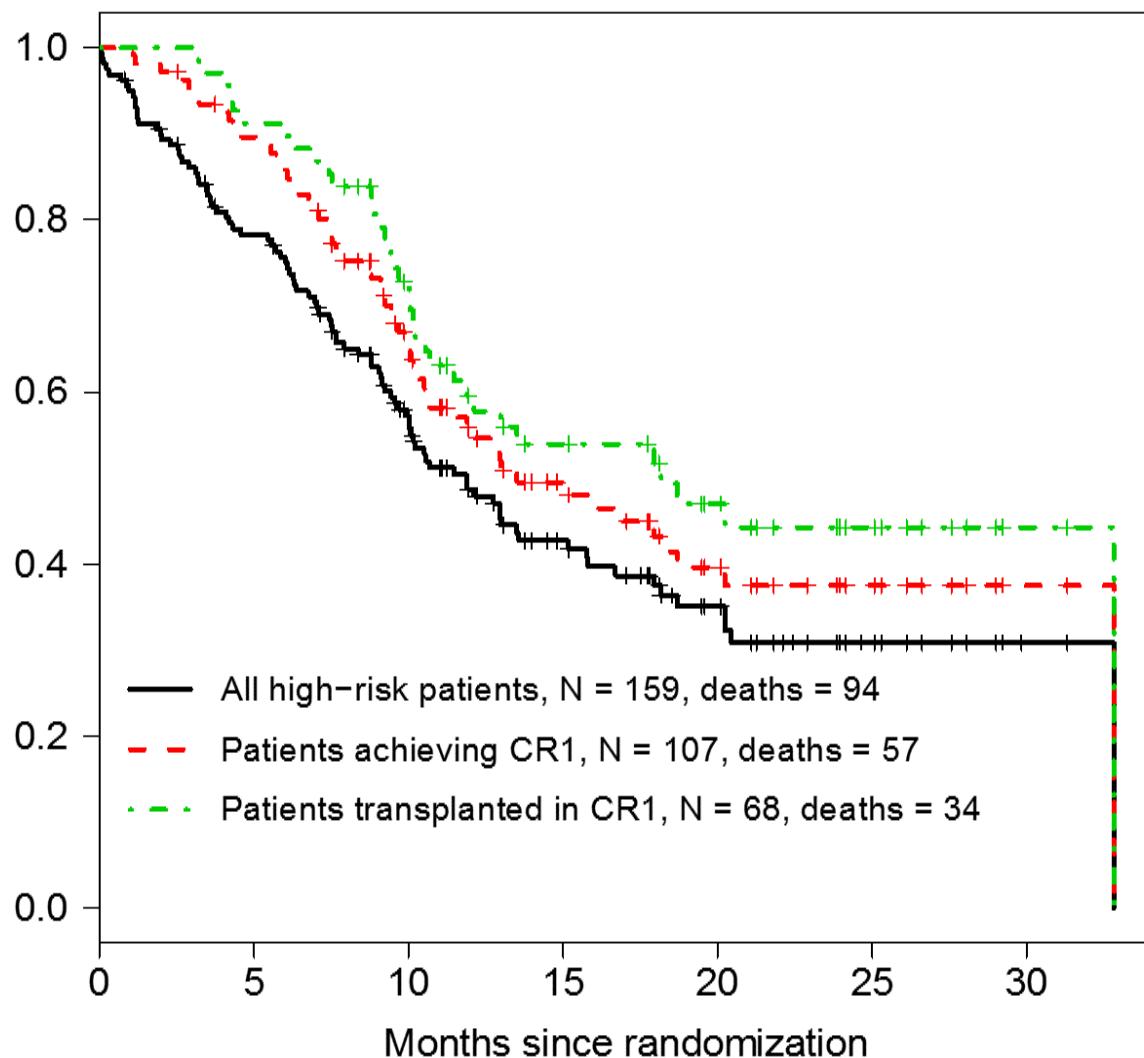
The turnaround time from the day the samples were shipped to the laboratory to the day the search was complete ranged from 4 to 24 days with an average of less than 9 days.

The results of the study were presented as an oral abstract at the 2016 ASH annual meeting. The study concluded that in newly diagnosed adults with AML age 18-60, early cytogenetic testing with an organized effort to identify a suitable allogeneic HCT donor led to a CR1 transplant rate of 64% in the high-risk group, which in turn led to a significant improvement in relapse free survival over historical controls. Better outcomes in poor prognosis AML patients may be achieved simply by rapidly finding unrelated donors and performing allogeneic HCT in CR1 as soon as possible.

Figure 11. Overall survival among all patients in the high-risk cohort, all high-risk patients achieving CR1, and in those high-risk patients transplanted in CR1.

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Overall survival, high-risk cohort



Immunogenetic Studies in Transplantation

HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In

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contingency situations, it will not be possible to delay transplant until a perfectly matched donor can be found.

Donor/Recipient Pair Project

A retrospective Donor/Recipient Pair HLA typing project to characterize class I (HLA-A, B and C) and class II (HLA-DRB, DQB1, DQA1, DPA1 and DPB1) alleles of stored donor/recipient paired samples was initiated in 1994. To date, over 25,000 unrelated paired samples and more than 1,300 related paired samples from the Repository have been fully characterized and the resultant data are available for research use. The data are stored in an NMDP developed database and is available to any researcher with a CIBMTR approved study wishing to analyze the impact of matching as either the focus of, or as a variable in a research study. To date, over 135 published research studies (not including abstracts) have used these data, including the seminal publication from Lee et al,¹⁰describing the importance of high resolution HLA matching in unrelated donor transplantation that formed the basis for NMDP's updated guidelines for unrelated adult donor HCT HLA matching.¹¹ The allele level data are also used to assess genetic diversity within the NMDP transplant population. Genetic diversity analyses have focused on the evaluation of HLA haplotypes within the donor and recipient data set made possible by the completeness of the major histocompatibility complex (MHC) loci characterized (11 loci), the level of resolution achieved and the high level of quality control. These studies have generated multiple manuscripts and abstracts to date with work still in progress. The statistical models developed for the project data were also applied to HapLogic, HapLogic II and HapLogic III.

In 2013, the typing strategy for the donor/cord and recipient samples being tested was significantly changed to take advantage of high quality results and the reduced cost of full panel high resolution typing including; HLA-A, B, C, DRB, DQB1 and DPB1 and presence/absence of 16 KIR loci. High resolution panel typing allows for sample identity confirmation thus resulting in the discontinuation of intermediate resolution typing. The project has continued to not type the DQA1 locus due to the greater than 98% linkage seen with DQB1 and continues high resolution DPB1 typing. Recent studies have demonstrated significant impact of permissive and non-permissive DPB1 matching on mortality.^{12,13} Exchange of DQA1 typing and addition of DPB1 typing did not impact the total cost.

Under this grant, HLA and KIR typing labs were contracted to type 3,262 unrelated and 1,354 related adult donor transplant pairs for the project. The majority of the samples were typed under a new NMDP Registry contract and a significantly reduced cost compared to prior grant years. , The cost per sample was reduced from approximately \$60 for HLA and KIR to \$47 per sample. In addition, the testing program was enhanced by moving to a full HLA gene sequencing approach rather than the targeted exon approach used in prior years. The full gene sequencing yields complete allele level typing in contrast to the antigen recognition domain (exons 2 and 3 for HLA class I and exon 2 for class II) high resolution typing. These data allow investigation of genetic regions not previously considered in donor/recipient matching. After successful completion of the typing, each pair was audited for

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use in analyses. All samples were selected in collaboration with the CIBMTR Statistical Center to ensure the additional cases would benefit ongoing and future analyses. Transplantation practices are constantly evolving and the project will continue to enroll the most recent transplant pairs to ensure that changes in practice can be evaluated with fully quality controlled high resolution HLA data. With the implementation of the IPR database, we continue to audit sample groups that contain both KIR and high resolution HLA to allow for inclusion in studies.

HLA-DPB1 crossover frequency analysis of HLA matched sibling Donor (MSD)/Recipient pairs

Previous studies have demonstrated a significant impact of DPB1 matching on aGVHD. The large genetic distance between the HLA-DPB1 locus and the remainder of the HLA loci may result in high rates of genetic crossover. Previously, the NMDP has not had access to samples to evaluate this phenomenon. The collection of a large cohort of HLA matched sibling donor transplant pairs through the CIBMTR Related Donor Repository provided the opportunity to explore the role of HLA-DPB1 crossover and resultant mismatch in allogeneic HCT.

A cohort of 1199 presumed MSD pairs, from 55 centers, collected by the CIBMTR Research Repository from 2007–2015 were typed. All pairs were reported to the CIBMTR as HLA identical siblings and received a transplant for either AML (44%), ALL (24%), MDS (26%) and 6% other diseases. The median patient age was 52, 59% were male, 86% received PBSC and 14% bone marrow. To determine the crossover frequency the subjects were typed by targeted exon NGS of exons 2 and 3 for both Class I and Class II yielding G group or better results, at HLA-A, B, C, DRB1, DRB3/4/5, DQA1, DQB1, DPA1 and DPB1. The results were analyzed under a subsequent grant.

Full HLA Gene Typing Match Assessment

The impact of amino acid differences outside of the ARD have not been previously evaluated in a retrospective analysis. During the grant period, a collaborative project was launched with the research laboratory at the Georgetown University Medical Center to generate complete HLA gene sequencing at HLA-A, B, C, DRB1, DQB1 and DPB1 on a cohort of previously characterized ARD identical at HLA-A, B, C, DRB1 and DQB1 unrelated donor/recipient pairs from the CIBMTR Research Repository.

A pilot cohort of 360 pairs was typed to assess the frequency of sequence disparities outside of the ARD and facilitate a sample size calculation for the final study cohort. The majority of the population was self-identified Caucasian (80%). The typing will be analyzed in a subsequent grant period.

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Donor/Recipient Pair Project KIR

While HLA matching is the most critical genetic determinant of HCT success, studies have found additional genetic determinants that may incrementally impact outcomes – for example, a correlation between KIR B content and relapse-free survival in AML. However, interpretations of association studies are complicated because the underlying haplotypic structures have not been elucidated. In particular, copy number ambiguities need to be investigated further. Only when these haplotypes are understood can more powerful association studies be conducted. More studies are needed to evaluate the roles of non-HLA loci in HCT.

In 2005, the NMDP Histocompatibility Committee conducted a literature review, and determined that the role of Natural Killer (NK) cells should be further evaluated in unrelated donor HCT. NK cells express immunoglobulin-like receptors (KIR), transcribed from genes located on chromosome 19, that specifically interact with MHC class I molecules and have been found to have anti-leukemic effects and protect against GVHD following allogeneic HCT.^{14,15}

KIR Copy Number Variation (CNV) Analysis

Our collective knowledge of structural diversity at the KIR gene level is still coarse, especially for unrelated and non-European populations. Dozens of structural haplotypes have been described for the KIR region. Most studies and typings have been conducted at gene presence/absence (PA) resolution, and transplantation guidelines are at the PA genotype level. We hypothesized that copy number typing could allow us to make more accurate haplotype predictions and therefore provide more refined haplotype frequencies and potentially increase resolution in association studies from the genotype level to the haplotype level.

Genotyping was performed at presence/absence for over 10,000 individuals in 5 populations: AFA, API, CAU, HIS, NAM. CNV testing was performed on 52% of AFA individuals in collaboration with the Traherne laboratory at Cambridge Institute for Medical Research, University of Cambridge.

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For our study we leveraged previous structural information given low-resolution genotypes, to perform experiments to quantify the effects of population variations, reference haplotypes, and genotyping resolution on population-level haplotype frequency estimations as well as predictions of individual haplotypes. A custom expectation maximization (EM) algorithm was used to estimate haplotype frequencies for each population by interpretation in the context of three sets of reference haplotypes. The algorithm also assigned each individual the haplotype pairs of maximum likelihood. Generally, our haplotype frequency estimates agree with similar previous publications to within <5% difference for all haplotypes. The higher-resolution CNV genotyping on the AFA samples allowed unambiguous haplotype-pair assignments for the majority of individuals. It was observed that typing resolution and reference haplotype set influence haplotype frequency estimates and we would recommend at that point, CNV must be typed for all genes.

These results were presented at the 2015 KIR Workshop in Southampton, England in September 2015.

Full KIR region sequencing

The most informative way to characterize the full KIR region is to sequence it from long single molecules. These whole region sequences provide the ability to experiment, discover, and annotate at highest resolution. They also provide indirect value as references, evolutionary informers, and source material for imputation.

Therefore, a collaboration was started between NMDP, Daniel Geraghty at Scisco Genetics and Pacific Biosciences with the aims of fosmid library construction, including content mapping and fosmid isolation, DNA sequencing of the fosmid clones using Pacific Biosciences long read technology, and determination of phase and full haplotype sequences.

We generated full-length sequences of the KIR region for 8 diploid individuals using a fosmid-based library preparation and sequencing on Pacific Bioscience's Single Molecule, Real-Time (SMRT™) sequencing.

Individuals had previously been typed at presence/absence, copy number, and SSO/SSP in the exons. The group was chosen for a balance of known/unknown haplotypes, insertion/deletion events, A/B content, and representation of the centromeric and telomeric regions. Fifteen of the sixteen haplotypes have been typed and submitted to GenBank. One individual was fully

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homozygous across both KIR haplotypes. These data were presented at the 2015 KIR Workshop in Southampton, England in September 2015.

17th International HLA and Immunogenetics Workshops (IHIW) collaboration

The NMDP collaborated with the IHIW KIR component to produce multiple replicates of a panel of 10 KIR defined reference samples from the pool of previously expanded high resolution KIR typed cell lines at the CIBMTR Research Repository. This panel will be used to qualify laboratories for participation in the IHIW KIR sequencing project. Laboratories received either DNA or viable cell lines as requested. The samples were selected for haplotypic diversity and alleles with large insertions and/or deletions. To date we have received presence absence typing from 7 of the 8 typing labs and CNV typing from 3. We have also started a collaboration with the DKMS typing laboratory in Dresden to confirm the allelic typing on 40 NMDP KIR high resolution typed reference cell lines. The results will be analyzed and presented at the 17th IHIW in 2017.

Antigen Recognition Domain (ARD) study

Amino acid mismatches outside the ARD (i.e., exons 2 and 3 for HLA class I and exon 2 for class II) are ignored under current HLA matching guidelines with the assumption that these differences are irrelevant. There is little data to confirm or refute this assumption; furthermore, the amount of data needed to form a conclusion is unattainable.²⁴ In order to provide more information, the ARD allo-reactivity assessment project will provide insight into the allowable percent tolerance of matching needed outside of the ARD. It is collaboration between the NMDP and Europdonor under the direction of Machteld Oudshoorn and Franz Claas from Leiden, Netherlands.

Initial investigation of the Class II ARD mismatch of DRB1*14:01 and DRB1*14:54 and DRB3*02:01 and 02:02 respectively have produced preliminary results demonstrating two weakly positive and one positive result. Interestingly, all positive results occurred in one direction only, which is DRB1*14:01 / DRB3*02:01 against DRB1*14:54 / DRB3*02:02. This data from the Cass II analysis was presented in an oral abstract¹⁶ at the 2013 EFI conference in Maastricht, Netherlands. To confirm these results, we identified 135 additional donors via registry queries. Fresh blood draws were collected from 22 donors and peripheral blood mononuclear cells cryopreserved for evaluation. All combinations tested showed no responses

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in the mixed lymphocyte culture whereas 4 out of 10 combinations were positive in the Elispot against the combined DRB1/DRB3 mismatch and only in one direction; DRB1*14:01/DRB3*02:01 against DRB1*14:54/DRB3*02:02. Positive responses were confirmed by primed lymphocyte testing (PLT) that was more sensitive than the Elispot. Furthermore, the PLT results suggested that the DRB1* mismatch was responsible for the response. In conclusion, mismatches involving positions outside the ARD are not very immunogenic. However, some mismatches can lead to T cell reactivity in vitro. The impact of these mismatches on clinical outcome of HCT remains to be established. The study results are currently being developed into a manuscript.

Analysis of four HLA Class I ARS mismatches; A*02:01 and 02:09, B*44:02 and 44:27, C*07:01, 07:06 and 07:18 have demonstrated that the selected pairs do not travel on the same haplotypes. A manuscript is under development.

Even when patient and donor are HLA matched, GVHD occurs, therefore, other loci may play a role.

- We completed the analysis of 16 KIR genomic haplotypes which resulted in over 130 new KIR alleles described, 15 GenBank submissions (1 homozygote) and 10 new ALT_LOCI alternate genome structures have been submitted for inclusion in future human genome patches.
- Presentations
 - KIR workshop 10 – 12 September, 2015, Winchester, UK
 - Maiers M, Louzoun Y. Bias in human offspring MHC due to selection for HLA genotypes with that share KIR ligands.
 - Pyo C-W, Eng K, Hall R, et al. 8 diploid sequences of the KIR region using single molecule, real-time sequencing.
 - Vierra-Green C, Roe D, Traherne J, et al. Effects of reference haplotypes and typing resolution in estimating haplotype frequencies in European, African-American, Native American, Hispanic and Asian populations.

Table 6 lists currently active and completed CIBMTR/NMDP-supported studies that are conducted on NMDP samples. The CIBMTR/NMDP encourages such collaborative projects and closely monitor them. Such studies are instrumental to understanding the role of non-HLA loci in HCT. The data is obtained and generated via NMDP donor and recipient research samples, along

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with their outcomes and demographics. The researchers are required to submit the interpreted results of all assays performed on the samples. The data submission requirement ensures that all sample testing yields information that is readily available to the HCT research community for subsequent analysis and eliminates or reduces duplicative testing to preserve resources and sample inventory. These results are stored in the IPR and IIDB databases, and associated with their samples in the CIBMTR Research Repository database.

Non-HLA data is available for use in research studies in a fashion analogous to the Donor/Recipient Pair Project generated HLA data and is made available, when possible, via the NMDP Bioinformatics web site. Data origin will be noted for all information stored, along with relevant citations. Access to the detailed data will be subject to the existing NMDP/CIBMTR data request procedures.

Table 6. Immunobiology typing projects utilizing NMDP samples and contributing data to the IPR database

Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
NK Cells, Their Receptors and Unrelated Donor Transplant ^{17,18}	J. Miller	2300 pairs	KIR	RT-PCR, FACS, SSO, MALDI-TOF	Yes
Survey of Diversity of Immune Response Genes in Unrelated Hematopoietic Stem Cell Transplantation	C. Hurley	40 Pairs	cytokine and KIR	SBT	Yes
Candidate Gene Study to Examine the Impact of Chemokine and Chemokine Receptor Gene Polymorphisms on the Incidence and Severity of Acute and Chronic GVHD ¹⁹	R. Abdi	1300 pairs	CCL1, CCL2, CCR5, CCR2, CX3CR1	Taqman PCR	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Functional Significance of Killer Ig-like Receptor (KIR) Genes in HLA Matched and Mismatched Unrelated HCT ²⁰	B. Dupont, K. Hsu	2000 pairs	KIR	SSP	Yes
Functional Significance of Cytokine Gene Polymorphism in Modulation Risk of Post-Transplant Complications ²¹	E. Petersdorf	2500 pairs	>30 Immune response genes	Taqman PCR	Yes
Identification of Functional SNPs in Unrelated HCT ²¹	E. Petersdorf	3500 pairs	Entire MHC region	Taqman PCR	In Process
Use of Female Donors with Pre-existing Antibody to H-Y Antigen will Result in Robust Serologic Response to H-Y Antigens in Male HSC transplantation Recipients ²²	D. Miklos	288 pairs	H-Y Antigen	ELISA, protein array	Yes
Multiplexed Genotyping of Human Minor Histocompatibility Antigens (mHAg): Clinical Relevance of mHAg Disparity in Stem Cell Transplantation ²³	T. Ellis	730 pairs	mHAg	Allele-specific Primer Extension	Yes
Genetic Polymorphisms in the Genes Encoding Human Interleukin-7 Receptor- α : Prognostic significance in Allogeneic Stem Cell Transplantation ²⁴	K. Muller	851 pairs	IL-7	Taqman PCR	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
The Effect of Non-Inherited Maternal Antigens in Cord Blood Transplantation ³⁶	L. Baxter-Lowe	102 pairs	HLA	SBT	Yes
Detection of HLA Antibody in Single Antigen HLA-Mismatched Unrelated Donor Transplants	S. Arai, D. Miklos	200 pairs	Anti-body	ELISA, Protein array	Yes
Detection of Donor-Directed, HLA-Specific Alloantibodies in Recipients of Unrelated Stem Cell Transplantation and Their Relationship to Graft/Patient Outcome ²⁵	R. Bray	111 pairs	Anti-bodies	Flow cytometry	Yes
Genome-wide Association in Unrelated Donor Transplant Recipients and Donors: A Pilot Study ²⁶	R. Goyal	858 pairs	> 600,000 Genome wide SNPs	Human 610 - Quad V1 arrays	Yes
SNPs in the p53 Pathway and Outcomes in URD HCT	B. DuPont	1500 pairs	p53, ATM, MDM2 and p21/Waf1	Taqman	In process
Association of Donor and Recipient Gene Polymorphisms of Drug and Innate Immune Response with Outcomes after URD HCT	V. Rocha	725 pairs	GSTP, GSTT, GSTM, UGT CD14, TIRAP, and NALPs	Taqman	Yes
To Develop and Test a Prognostic Index for Survival in CML URD HCT ²⁷	A. Dickinson	1100 pairs	TNF, IL-1RA and IL-10	Taqman	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Evaluation of TGF-β1 Promoter and Signal Peptide Polymorphisms as Risk Factors for Renal Dysfunction in HCT Patients Treated with Cyclosporine A ²⁸	R. Shah	400 samples	TGF-β1	Taqman	Yes
Donor and Recipient Telomere Length as Predictors of Outcomes after Hematopoietic Stem Cell Transplant in Patients with Acquired Severe Aplastic Anemia ^{29,30}	S. Gadalla	650 samples	Telomere length and Telomerase Polymorphisms	Taqman	Yes
Development of a GVHD Prevention Biodiagnostic Test	R. Somogyi	450 samples	Gene Expression Array	Array	Yes
Genetic polymorphisms and HCT related mortality Re: Pre-HCT conditioning in matched unrelated donor HCT ³¹	T. Hahn	>4,000 pairs	GWAS	Array	In process
Impact of CTLA4 SNPs on outcome after URD transplant ³²	M. Jagasia	1,200 pairs	CTLA-4 SNPs	Taqman	Yes
KIR genotyping and immune function in MDS patients prior to unrelated donor transplantation ³³	E. E.Warlick and J. Miller	970 samples	KIR genotype, expression and cellular function	SSP, flow cytometry and cellular assays	In process
Plasma YKL-40 and CHI3LI genotype to predict mortality after unrelated donor HCT ³⁴	B. Kornblit	800 pairs	YKL-40 plasma levels and CHI3LI SNPs	ELISA and Taqman	Yes
Natural killer cell genomics and outcomes after allogeneic transplantation for lymphoma ³⁵	V. Bachanova, J. Miller, D. Weisdorf and L. Burns	800 pairs	KIR genotype, expression and cellular function	SSP, flow cytometry and cellular assays	Yes

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Effect of genetic ancestry matching on HCT outcomes	A. Madbouly, M. Maiers and N. Majhail	2300 pairs	Ancestry Informative Markers	Taqman GWAS	Yes
Impact of MHC Class I chain related polymorphisms on HCT outcomes	M. Askar and R. Sobecks	700 pairs	MICA genotypes	Taqman	Yes
Impact of donor signal-regulatory protein alpha polymorphism on HCT outcome	A. Gassas, J. Danska and S. Rajakumar	400 pairs	SIRP- α SNPs	Taqman	In process
Discrepancy analysis of microsatellite loci as a proxy measure for ancestral differentiation	J. Harvey, C. Steward and V. Rocha	800 pairs	Microsatellites and STR	Taqman	In process
Prognostic impact of somatic mutation and the levels of CXC chemokine ligands in MDS	W. Saber, R.C. Lindsley and B. Ebert	1300 pairs	Chemokine levels Somatic mutations	ELISA Sequence capture	Yes
Mitochondrial DNA haplotypes and outcome	M. Verneris and J. Ross	4000 pairs	SNPs	Taqman	In process
Assessing T cell repertoire similarity in HLA mismatched HCT	E. Meyer	50 samples	TCR repertoire sequence	NGS	In process
Impact of SNPs in the Gamma Block of the MHC	M. Askar and R. Sobecks	700 pairs	SNPs	Taqman	In process
Clinical outcomes among HCT recipients as a function of socioeconomic status and transcriptome differences	J. Knight, J.D. Rizzo and S. Cole	252 samples	Gene expression array	Array	In process
Natural killer cell genomics and outcomes after HCT for CLL	V. Bachanova, J. Miller, D. Weisdorf and S. Cooley	600 samples	KIR genotype	SSP	In process

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Study Title	Investigator	Number of Samples	Genes of interest	Testing Method	Data submitted
Donor telomere length and outcomes after HCT for acute leukemia	S. Gadalla, S. Savage, D. Loftus and E. Hytopoulos	1145 samples	Leukocyte telomere length	qPCR	In process
KIR gene content and pediatric acute leukemia HCT outcome	M. Verneris, J. Miller and S. Cooley	500 samples	KIR genotype	SSP	In process
Functional genetic variants of the ST2 gene in pairs of recipient and donors for risk stratification of GVHD and TRM outcomes.	S. Paczesny and S. Spellman	1000 pairs	sST2	Taqman	In process

Clinical Research in Transplantation

Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

Observational Research

Through the CIBMTR Working Committee structure, which incorporates many highly successful researchers in clinical transplantation, the NMDP expanded its research activities to increase scientific knowledge of blood and marrow transplantation. This was accomplished by performing retrospective studies to identify the most promising transplant approaches, and by identifying the patients most likely to benefit from this therapy. In addition, research in immunobiology was conducted to better understand how transplantation works including how to harness the power of the immune system to control cancer.

The CIBMTR collects data for approximately 19,000 new transplant recipients annually as well as a continually increasing volume of follow-up data on previously reported recipients and donors. Figure 11 shows cumulative accession of transplants since 1970 when the International Bone Marrow Transplant Registry began collecting these data. These data are the basis for the CIBMTR Observational Research program and are accessed by the Working Committees to conduct studies.

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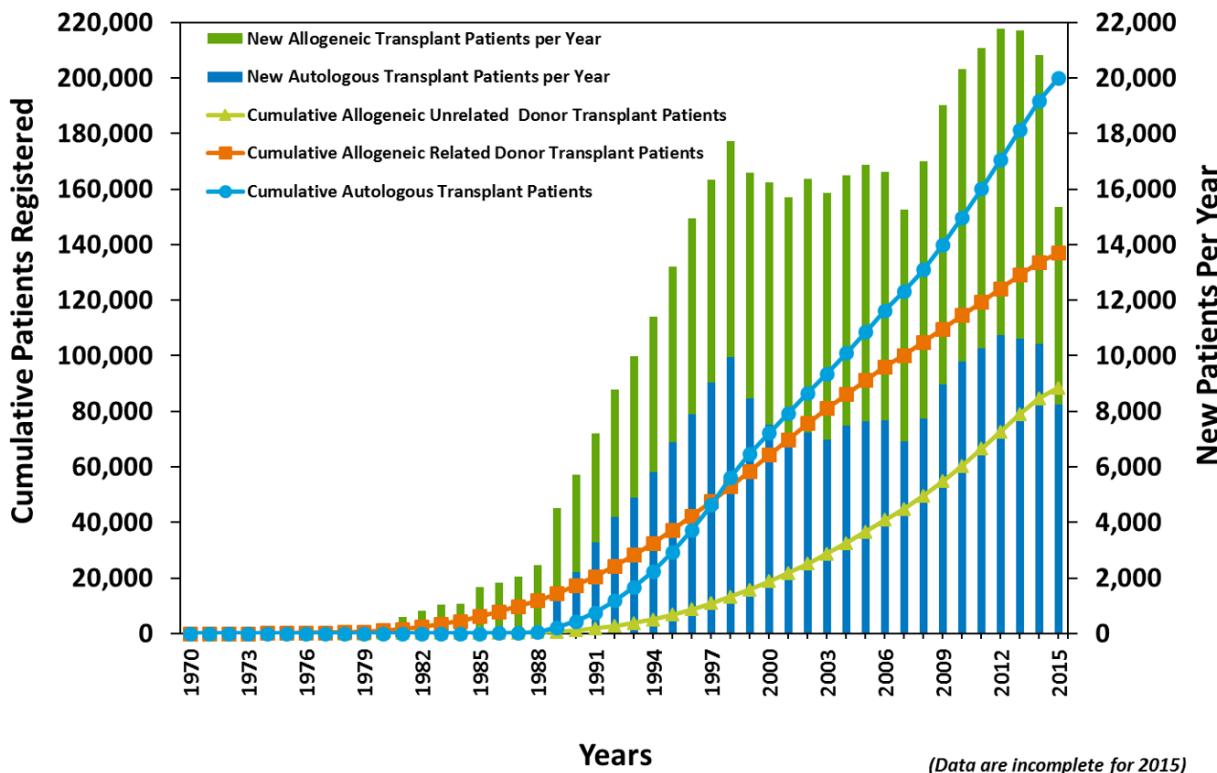


Figure 11. Accession of Transplant Recipients Registered with the CIBMTR

Currently, there are 15 Working Committees within the CIBMTR with 204 active studies in progress (46 in manuscript preparation and 158 in various states of completion). In 2015, the CIBMTR published a total of 81 peer-reviewed publications (38 working committee studies, 14 Coordinating Center, 4 Health Services Research, 8 BMTCTN, 5 Statistical Methods and 12 Bioinformatics) (Figure 12). Sources of funding for these studies vary by investigator, but the majority use NMDP resources and CIBMTR statistical support.

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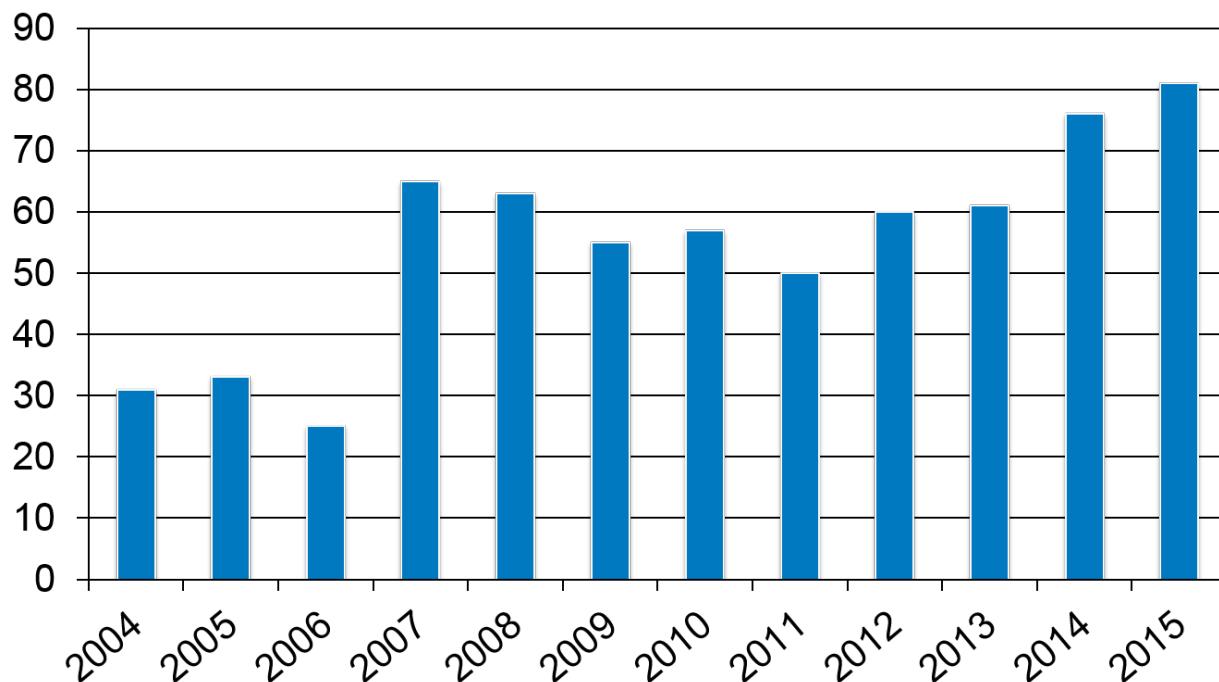


Figure 12. CIBMTR peer-reviewed publications by year.

Clinical Trials

In October 2010, RCI BMT activated a study referred to as the Long Term Donor Follow up study. The primary goal of this study is to evaluate the hypothesis that the incidence of targeted malignant, thrombotic and autoimmune disorders after unrelated hematopoietic stem cell donation are similar between unstimulated BM and filgrastim-mobilized PBSC donors. Once the donor has consented to participate, the donor is contacted and asked study specific questions every other year. This will continue until study completion which is estimated to be 2020. If the donor reports an incidence of interest, a request for their medical records is made. Cases of targeted disorders are reviewed by the medical monitors to confirm the veracity of the report.

In October 2015, accrual to this study was closed, follow-up assessments will continue until the end of 2020. The table below summarizes the accrual by cohort and product. The SRG team is responsible for the follow up assessments of just over 63% of the enrolled donors. To date the SRG has completed a total of 23,483 assessments of which 7237 were during this past year.

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Table 7. Long Term Donor Follow-up Study accrual summary

	Marrow	PBSC	Both	Total
Prospective Cohort	3003	8853	141	11997
Retrospective Cohort	3841	5467	374	9682
Waiting for Collection	113	296	0	409
Totals	6957	14816	515	22288

Other Clinical Research activities

In 2014, we explored options for a) comprehensive system for management of activities and studies within the Survey Research Group (SRG) and b) electronic data capture system (EDC) and clinical trial management system (CTMS) to coordinate operational and administrative activities within RCI BMT. In March 2015 the (SRG) Call tracking system built within SalesForce platform went into production. In June 2015, we initiated work on implementing Medidata RAVE for our EDC system and their CTMS solution for our internal trial management activities.

SRG solution:

SRG's new system had an immediate and significant impact on SRG's efficiency. It allows Survey Research Associates to schedule and complete their contact activities (calls, emails, letters) in the same place, provides staff with a daily list of tasks that they can start on with minimal preparation, and provides streamlined communication of relevant notes about individual study subjects. Just prior to launching Salesforce, SRG had five Survey Research Associates.

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Today, the group has three Survey Research Associates, who comfortably accomplish a similarly sized workload.

The Salesforce call tracking system has also produced great efficiencies for the SRG Supervisor through its data reporting and management capabilities. The system has reduced about 20% of the Supervisor's time related to subject management, quality checks of her staff's work, and staff training.

SRG has also been able to add new studies to the call tracking system in a much more efficient and consistent manner than was possible with previous call tracking systems.

Cord Blood research initiatives

During the project period, the Cord Blood Research Sub-advisory Group met semi-monthly to discuss study priorities and plan analyses for the following:

Cord Blood Bank Proficiency Testing

The NMDP facilitates a proficiency testing (PT) program for network cord blood banks (CBB). The purpose of this program is to monitor and evaluate the accuracy of a CBB's assay performance and analysis through inter-CBB comparisons. The program was initiated in 2004 and distributes one testing panel annually. Initially, the program reflected the local testing of individual CBBs who performed the assays according to their internal protocols. Due to the highly subjective nature of the colony forming unit (CFU) assay, this resulted in very little inter-CBB consensus of results. To address the poor consensus for the CFU assay, the program was modified to require that the participants use a standardized protocol and reagents distributed by Stem Cell Technologies (SCT), thereby controlling the introduction of variability in testing results from the use of different CFU protocols. In the current form of the program, participants are instructed to perform, analyze, and report results for the following assays: total nucleated cell count (TNCC), %CD34+ cells gated on viable cells, %CD34+/CD45+ gated on viable cells, and colony forming unit enumeration and identification. Throughout the years of the program, the inter-CBB coefficient of variation (CV) has remained high for the enumeration of CFUs, despite efforts to control for this, as evidenced by the PT data analysis from 2014.

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Table 8. Aggregate results of the 2014 cord blood Proficiency Testing program

	N	Mean	SD	CV	Median	Range
BFU-E	30	17.77	6.88	38.69	16.88	10.90-24.65
CFU-GM	31	18.31	5.74	31.37	17.75	12.57-24.05
CFU-GEMM	29	2.26	1.72	76.18	2.50	0.54-3.98
Total Colonies	33	35.33	14.23	40.28	37.50	21.10-49.56

The NMDP Cord Blood Advisory Group (CBAG) raised concerns about the current program because the SCT CFU protocol used by participants does not reflect the CBB's standard methodologies. The results of the SCT CFU protocol testing only assesses the participants proficiency in performing an assay on an annual basis in a manner that is not consistent with the methodologies used to report product characteristics through Emtrax for use in CBU selection algorithms by TCs.

The College of American Pathologists (CAP) administers a PT program where the CFU assay is performed using local CBB protocols. However, the data analysis provided through the CAP program is limited and does not capture sufficient information to compare differences between testing methodologies, reagents, and instruments used by the various participants. In addition, very few CBBs participate in the CAP program making consensus analyses difficult to perform.

The Cord Blood Research Sub-advisory group started work on a re-design of the 2015 administered PT program to compare testing results generated using CBB in-house methodologies, reagents, and instruments (Study Arm) compared to the use of the standardized SCT protocol and reagents (PT Arm) on a standardized sample. The standardized sample was red blood cell depleted, which was not characteristic of all previous send-outs. A survey was created and sent to CBBs participating in the study to capture characteristics of the in-house testing

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methods. The survey results will facilitate an evaluation inter-CBB differences in testing approaches in general and any data consensus issues that may be the result of these differing approaches. Data was analyzed by SCT and returned to the sub-group late summer of 2015.

Forty three individuals from 24 different institutions submitted data for the PT Arm. Twenty five individuals from 14 different institutions submitted data for the Study Arm. Fifteen institutions completed the Study Arm survey. The variability in CFU counts was analyzed within a subgroup of participants who submitted data for both the Study and PT Arms (N=25).

Results of the survey, depicted in the table below, indicate most institutions plate total nucleated cells (87%), as opposed to white blood cells. 53% use 35mm Dish to plate, while 20% use 6 well plates. 53% use a 1 to 10 dilution when adding cells to the media tube. Most responders (73%) reported identifying and counting blast forming unit-erythrocytes (BFU-E), colony forming unit granulocyte macrophage (CFU-GM), and colony forming unit-gran erythrocyte macrophage monocyte (CFU-GEMM). The survey revealed some variability between participants' in house methods; however, the effect of variables could not be assessed due to small size of specific cohorts.

Table 9. Results of 2015 Proficiency Testing program survey

Question	Response	% Response
Type of cells plated	WBC	13
	TNC	87
Viability assessment method	Trypan Blue	40
	7-AAD	40
	NA	20

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Type of plates/wells for CFU assay	35mm Dish	53
	6 Well Plates	20
	SmartDish	13
	24 Well Plates	13
Number of replicates plated per sample	1	7
	2	60
	3	27
	4	7
Volume of cells inoculated into MethoCult	1/10 of media	53
	Variable/Other	47
Method to mix the cells into the semi-solid media	Vortex	93
	Pipetting	7
Method for dispensing the semi-solid medium into well/plate	Needle/Syringe	100
Cord blood processing method	Sepax	47
	AXP	20
	PrepaCyte	13
	Manual	7
Day of colony enumeration	14d	100
CFU counting method	Manual	80
	Automated	20
	BFUE/GM/GEMM	73

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CFU colony types identified and counted	Total CFU	7
	Other	20

Analysis of the results of the PT Arm are shown in Table 10. All parameters measured showed a % coefficient of variation lower than 25% except for enumeration of CFU-GM (33.73%CV) and CFU-GEMM (58.50%CV). The % coefficient of variations were the lowest for total CFU, TNC, and CD34+ assessments within the past eight years and may be explained by the use of the RBC-depleted sample.

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Table 10. Results of the 2015 Proficiency Testing program evaluation using the standardized protocol (PT Arm)

	N	Mean*	Standard Deviation*	% Coefficient of Variation	Median
Total Nucleated Cells (x10⁶ cells)	42	10.89	0.51	4.71	10.86
Viability (%)	42	95.95	2.00	2.08	96.28
Viable Nucleated Cells (x10⁶ cells)	42	10.44	0.41	3.94	10.39
%CD34⁺ Gated on Viable Cells	13	0.22	0.022	10.09	0.23
%CD34⁺+CD45⁺ Gated on Viable	25	0.24	0.036	14.72	0.25
BFU-E	40	16.56	4.10	24.76	16.50
CFU-GM	41	17.45	5.89	33.73	17.00
CFU-GEMM	39	2.77	1.62	58.50	2.75

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Total Colonies	41	38.02	8.64	22.73	37.00
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*Robust analysis

The total colony enumeration results of the participants of the PT and Study Arms are detailed in the table below. Of note is the difference in % coefficient of variation between the two arms: 18.67% and 40.49%, PT Arm and Study Arm, respectively. However, the difference between the CFU results from the two arms is not statistically significant when analyzing the normalized total CFU (p-value = 0.9467).

Table 11. Comparison of results between the PT and Study arms

	N	Mean*	Standard Deviation*	% Coefficient of Variation	Median
PT Arm	25	117.18	21.88	18.67	109.17
Study Arm	25	104.21	42.20	40.49	98.39

*Robust analysis

The Cord Research Sub-advisory Group determined that more evaluation needs to be conducted before recommendations can be made regarding the CFU assay.

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Dextran Shortage Response

In late 2014 the CBAG was informed of an impending shortage of clinical grade Dextran solution that was caused by a manufacturing issue at the primary supplier. Dextran is utilized by TCs during the thaw and wash preparation of CBUs prior to infusion and is a critical component of the thaw protocols developed by CBBs. The Cord Research Sub-advisory Group was tasked with seeking alternatives to standard dextran solution that would meet FDA requirements.

A sample of transplant centers (TC) were surveyed to determine their process to compare these alternatives. The TCs were then asked to share their comparability protocols for review. The 12 TCs that responded to the survey studied various types of alternative reagents and manufacturers of the standard Dextran 40 in 0.9% NaCl. Four TCs submitted their protocols to the Sub-advisory group from which a model comparability protocol was created for centers who need assistance. Whether comparing Dextran 40 in 0.9% NaCl to that of a different manufacturer or a different reagent, the results of the comparability studies submitted by the TCs indicated equivalency. During a shortage, the model comparability study protocol can be used as a reference to establish an alternative to Dextran 40 in 0.9% NaCl. This information was disseminated to NMDP network partners by a network announcement and can be currently found at the link:

<https://network.bethematchclinical.org/WorkArea/DownloadAsset.aspx?id=13620>.

Immunobiology Research

During a previous grant period, the NMDP developed the Immunobiology Research grant request and award procedures for use by the IBWC and developed the IBWC Web site (http://www.cibmtr.org/COMMITTEES/Working_Committees/Immunobiology/index.html). The content was further refined and migrated to the CIBMTR.org Web site in 2010 and is refreshed annually.

IBWC 2014-2016 (October 1, 2014-September 30, 2016) manuscripts (submitted/accepted):

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CIT Minneapolis Initiatives

The scope of the work performed by the CIBMTR IT department in Minneapolis includes collecting and reporting outcomes data on all allogeneic transplantations performed in the U.S. (for the SCTOD, as required by U.S. law). U.S. transplant centers also voluntarily submit autologous transplantation data, and transplant centers worldwide voluntarily submit both autologous and allogeneic transplantation data. As a result, and as reported in the CIBMTR 2015 Annual Report, the CIBMTR Research database now contains information on more than 425,000 patients. CIT strives to provide applications that will reduce center burden for government mandated forms and provide high quality data on demand.

CIT Application Suite:

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- FormsNet: Recipient – Donor
- AGNIS
- Management Reporting
- Sample Tracking
- Auditing

FormsNet

Since its original release in Dec 2007, the Recipient Module of the FormsNet application has been used at more than 418 centers to register 183,198 patients and collect over 1,242,313 forms with more than 10 million data elements. This program was developed for both local data entry from paper forms and web-based entry by clinical centers. Currently over 94.9% of the data are being entered by clinical centers via the web. In the last six months, NMDP derived 99% by calculating forms submitted electronically divided by those forms eligible for electronic submission. Two forms (2801 – log of appended documents and 2802 – transfer forms) can only be submitted on paper to ensure audit standards. The Form 2801 – log of appended documents, is in process of being decommissioned as a new feature has been added to FormsNet3 proving the ability to attach electronic documents directly to a form.

FormsNet is a secure, Web-based application for submission of outcomes data to CIBMTR (Recipient module), support for Auditing and Event Reporting, and support for Donor clearance, follow-up and safety (Donor module). The original features of real-time error validation and override capabilities, and the option to generate a Forms Due Report to track all forms due for every patient have been improved and enhanced. The original deployment in December 2007 was built in 126,000 lines of code supporting 90 Recipient forms and no user tools. Today there are over 500,000 lines of code supporting 249 forms, tools, web services, email, and two user-based modules. The application is fully integrated with the CIT applications suite supporting CIBMTR. The application was converted from its original website to a web application with an enhanced object oriented code structure. Service Oriented Architecture integration services were created to provide flexibility and extensibility for future enhancements. In 2012, the planned upgrade to FormsNet replaced the technical foundation of the current FN2 application, with more agile, efficient & effective systems. It improved the user experience by providing enhanced functionality (defined by the network users). In 2014, the Donor module was upgraded to the FormsNet 3 platform, providing the same benefits for Donor module users as realized by Recipient module users. FormsNet was updated monthly during the reporting period to enhance the Recipient, Donor, and Audit modules to apply enhancements and ensure optimal performance, flexibility and efficiency of applications. The Recipient module was also enhanced to support the long-term strategic goal of facilitating data collection for non-transplant therapies. The new Indication for CRID assignment form was added to streamline the patient registration process by separating the unique ID assignment from collection of initial treatment information, and to facilitate ease in collection of indications including non-transplant therapies.

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RITN

As part of the RITN preparedness efforts, Institutional Review Board-approved protocols are in place at multiple RITN centers for the collection of demographic, situational and clinical data from radiation casualties who are sent to RITN hospitals and provide informed consent. The CIBMTR is uniquely positioned to collect this data, based on the existing data collection system and the program's long track-record of collecting similar data on more than 22,000 blood and marrow transplant recipients annually. Importantly, the data collection approach for radiation casualties will differ from that which is collected daily in CIBMTR centers since only those who receive a transplant are tracked in the current system. This data collection process will not only capture those who undergo blood and marrow transplantation but also all radiation casualties treated at RITN centers and provide informed consent. The data obtained from the RITN Data Collection Interface will be an invaluable resource for subsequent efforts to improve triage, treatment and monitoring approaches for individuals exposed to radiation.

In 2014, CIBMTR performed analysis and design to support the RITN data collection needs. This included confirming the overall scope, interviewing key stakeholders, identifying business needs/requirements, defining required forms and other key design elements essential to begin development early in FY15. RITN development continued during FY15, including building the Contact, Baseline, and Follow-up Forms to collect the required data points, as well as testing the application. The production rollout was completed in early FY16 under a subsequent grant.

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IX. Acronyms

AABB	American Association of Blood Banks
AAFA	African American (NMDP race code)
AAR/IP	After Action Review/Improvement Plan
ABA	American Burn Association
ABD	Antigen Binding Domain
ABMTR	Autologous Blood and Marrow Transplant Registry
AC	Apheresis Center
AFA	African American
AFB	African
AFRRI	Armed Forces Radiobiology Research Institute
AGNIS®	A Growable Network Information System
AHA	American Hospital Association
AHLS	Advanced HAZMAT Life Support
AIM	Ancestry Informative Markers
AINDI	South Asian
AISC	American Indian South or Central
ALANAM	Alaska Native or Aleut
ALD	Asymmetric Linkage Disequilibrium
ALDH	Aldehyde Dehydrogenase
ALDHbr	Aldehyde Dehydrogenase bright

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ALT-LOCI	Alternate Loci
AMIND	North American Indian
AML	Acute Myelogenous Leukemia
AMR	American Indian
ANSI	American National Standards Institute
API	Application Programming Interface
AQP	Ancestry Questionnaire Project
ARC GIS	ArcGIS is a brand name: GIS = Geographical Information System
ARD	Antigen Recognition Domain
ARRA	The American Recovery and Reinvestment Act of 2009
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)
ARS	Antigen Recognition Site
ASBMT	American Society for Blood and Marrow Transplantation
ASEATTA	Australian and South East Asian Tissue Typing Association
ASH	American Society for Histocompatibility
ASHG	American Society of Human Genetics
ASHI	American Society for Histocompatibility and Immunogenetics
ASI	Asian American
ASPR	Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
AUC	Area Under Curve
B-LCLs	B-Lymphocytic Cell Lines
B2B	Business to Business
BAA	Broad Agency Announcement
BARDA	Biomedical Advanced Research and Development Authority
BBMT	Biology of Blood and Marrow Transplantation
BCP	Business Continuity Planning
BCPeX	Business Continuity Plan Exercise
BFU-E	Burst Forming Unit-Erythrocytes
BGI	Beijing Genome Institute
BISC	Bioinformatics Integration Support Contract
BM	Bone Marrow
BMCC	Bone Marrow Coordinating Center
BMDW	Bone Marrow Donors Worldwide
BMT	Bone Marrow Transplant/Transplantation
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network
BODI	Business Objects Data Integrator
BRAGG	Bioinformatics Research Advisory Ginger Group
BRIDG	Biomedical Research Integrated Domain Group

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BRT	Basic Radiation Training
BTM	Be The Match
caBIG	NIH/NCI Cancer Biomedical Informatics Grid
caDSR	Cancer Data Standards Repository
C&A	Certification and Accreditation
CAP	College of American Pathologists
CARB	Black Caribbean
CARHIS	Caribbean Hispanic
CARIBI	Caribbean Indian
CATI	Computer Assisted Telephone Interviewing
CAU	Caucasian
C&A	Certification and Accreditation
CB	Cord Blood
CBA	Cord Blood Association
CBAG	Cord Blood Advisory Group
CBITT	Center for Biomedical Informatics and Information Technology
CBMTG	Canadian Blood and Marrow Transplant Group
CBB	Cord Blood Bank
CBC	Congressional Black Caucus
CBS	Canadian Blood Service
CBT	Cord Blood Transplantation
CBU	Cord Blood Unit
CC	Collection Center
CCD	Continuity of Care Document
CD	Cluster of Differentiation
CDA	Clinical Document Architecture
CDC	Centers for Disease Control
CFU	Colony Forming Unit
CDE	Common Data Elements
CDISC	Clinical Data Interchange Standards Consortium
CEM	Certified Emergency Manager
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CEP	Collect Eject Protect
CFU	Colony Forming Unit
CFU-GM	Colony Forming Unit-Granulocyte Macrophage
CFU-GEMM	Colony Forming Unit-Gran Erythrocyte Macrophage Monocyte
CG-WG	Clinical Genomics Work Group
cGy	CentiGrey

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CHORI	Children's Hospital of Oakland Research Institute
CHOP	The Children's Hospital of Philadelphia
CHS	Certified Histocompatibility Specialist
CHTC	Certified Hematopoietic Transplant Coordinator
CIBMTR®	Center for International Blood & Marrow Transplant Research
CIO	Chief Information Officer
CIT	CIBMTR Information Technology
CLIA	Clinical Laboratory Improvement Amendment
CMCR	Centers for Medical Countermeasures Against Radiation
CMDP	China Marrow Donor Program
CME	Continuing Medical Education
CMF	Community Matching Funds
CML	Chronic Myelogenous Leukemia
CMO	Chief Medical Officer
CMS	Center for Medicare and Medicaid Services
CMV	Cytomegalovirus
CNV	Copy Number Variation
COG	Children's Oncology Group
CPA	Center Performance Analytics
CPI	Continuous Process Improvement
CREG	Cross Reactive Groups
CRF	Case Report Forms
CRID	CIBMTR Recipient ID
CRIS	Computerized Repository Inventory System
CRO	Chief Recruitment Officer
CSF	Colony Stimulating Factors
CSO	Chief Strategy Officer
CSS	Center Support Services
CSS	Custom Search Support
CT	Confirmatory Testing
CTA	Clinical Trial Application
CTLp	Cytotoxic T Lymphocyte Precursor
CTMS	Clinical Trial Management System
CUPC	Cisco Unified Personal Communicator
CV	Co-efficient of Variations
CWD	Common Well Documented
DAIT	Division of Allergy, Immunology, and Transplantation
DaSH	Data Standards Hackathon
DC	Donor Center

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DCAA	Defense Contract Audit Agency
DFCI	Dana-Farber Cancer Institute
DHHS	Department of Health and Human Services
DIY	Do It Yourself
DKMS	Deutsche Knochenmarkspenderdatei
DMSO	Dimethylsulphoxide
DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOE	Department of Energy
DP	Domain Prediction
DQ	Data Quality
DR	Disaster Recovery
D/R	Donor/Recipient
DRPP	Donor Related Pair Project
DSA	Donor specific anti-HLA antibody
DSMB	Data Safety Monitoring Board
DSTU	Draft Standard for Trial Use
DVD	Digital Video Disc
EBMT	European Group for Blood and Marrow Transplantation
EC	Ethics Committee
ED	Emergency Department
eDBiC	Enhanced Data Back to Centers
EDC	Electronic Data Capture
EFI	European Federation for Immunogenetics
EHR	Electronic Health Record
ELISA	Enzyme-linked Immunosorbant Assay
ELIspot	Enzyme-linked Immunosorbent Spot
EM	Expectation Maximization
EMDIS	European Marrow Donor Information System
EMR	Electronic Medical Records
EMS	Emergency Medical System
ENS	Emergency Notification System
ERSI	Environment Remote Sensing Institute
ESRI	Environmental Systems Research Institute
EUR	European American
E-utilities	Entrez Programming Utilities
FACS	Fluorescent Activated Cell Sorting
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration

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FDR	Fund Drive Request
FGM	France Greffe de Moelle
FHCRC	Fred Hutchinson Cancer Research Center
FHIR	Fast Healthcare Interoperability Resources
FILII	Filipino
FLOCK	Flow Cytometry Analysis Component
FN	FormsNet
FN3	FormsNet3
Fst	Fixation Index
FWA	Federal-wide Assurance
FY	Fiscal Year
GEMM	Granulocyte, Erythrocyte, Monocyte/macrophage, Megakaryocyte
GETS	Government Emergency Telecommunications Service
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)
GDRGEN	Group (HLA)-DR Generic
GETS	Government Emergency Telecommunication Service
GIS	Geographic Information System
GL	Genotype List
GM	Granulocyte Macrophage
GM-CSF	Granulocyte Macrophage Colony Stimulating Factor
GS	General Services
GTR	Genetic Testing Registry
GUI	Graphical User Interface
GVHD	Graft vs. Host Disease
GWAS	Genome Wide Association Studies
GWASH	Genome-Wide Association Scan for Histocompatibility Antigens
Gy	Gray-measure of dose of irradiation
HARPs	HLA Ambiguity Resolution Primers
HAWI	Hawaiian or other Pacific Islander Unspecified
HAZMAT	Hazardous Material
HBCU	Historical Black Colleges and University
HC	Hematopoietic Cell
HCS®	Health Care Standard
HCT	Hematopoietic Cell Transplantation
HEPP	Hospital Emergency Preparedness Program
HHQ	Health History Questionnaire
HHS	Health and Human Services
HIEDFS	HLA Information Exchange Data Format Standards
HIPAA	Health Insurance Portability and Accountability Act

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HIS	Hispanic
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
HML	Histoimmunogenetics Mark-up Language
HR	High Resolution
HRSA	Health Resources and Services Administration
HSC	Hematopoietic Stem Cell
HSCT	Hematopoietic Stem Cell Transplant
HSR	Health Services Research
HTML	HyperText Markup Language
HWE	Hardy-Weinberg Equilibrium
IBMDR	Italian Bone Marrow Donor Registry
IBMTR	International Bone Marrow Transplant Registry
IBWC	Immunobiology Working Committee
ICRHER	International Consortium for Research on Health Effects of Radiation
ID	Identification
IDAWG	Immunogenetics Data Analysis Working Group
IDM	Infectious Disease Markers
IDS	Integrated Data Store
IDW	Integrated Data Warehouse
Ig	Immunoglobulin
IHW	International Histocompatibility and Immunogenetics Workshop
IHIWS	International Histocompatibility Work Shop
IHWG	International Histocompatibility Working Group
IIDB	Immunobiology Integration Database
IIMMS	International Immunomics Society
IMGT	ImMunoGeneTics
IMStrategy	Information Management Strategy
ImmPort	Immunology Database and Analysis Portal
IND	Investigational New Drug
IND	Improvised Nuclear Device
IPD	Immuno Polymorphism Database
IPR	Immunobiology Project Results
IRB	Institutional Review Board
IS	Information Services
ISO	International Organization for Standardization
IT	Information Technology
JAPI	Japanese
JCHO	Joint Commission of Healthcare Organizations

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JCAHO	Joint Commission on Accreditation of Healthcare Organizations
KIR	Killer Immunoglobulin-like Receptor
KORI	Korean
KT	Kiloton
LD	Linkage Disequilibrium
LEL	Low Expression Alleles
LOINC	Logical Observation Identifiers Names and Codes
LSSG	Life Sciences Strategy Group
LTA	Lymphotoxin Alpha
M	Million
MALDI-TOF	Matrix-Assisted Laser Desorption/Ionization – Time Of Flight
MBS	Masters of Biological Science
MCW	Medical College of Wisconsin
MD	Medical Doctor
MDACC	MD Anderson Cancer Center
MDHT	Model Driven Health Tools
MDS	Myelodysplastic Syndrome
MENAFC	MidEast/North Coast of Africa
mHAg	Minor Histocompatibility Antigen
MHC	Major Histocompatibility Complex
MICA	MHC Class I-Like Molecule, Chain A
MICB	MHC Class I-Like Molecule, Chain B
MIRING	Minimal Information for Reporting Immunogenomic NGS Genotyping
MKE	Milwaukee
MLC	Mixed Lymphocyte Culture
MLR	Mixed loss Ratio
MOU	Memorandum of Understanding
MRD	Minimal Residual Disease
MSD	Matched Sibling Donor
MSKCC	Memorial Sloan-Kettering Cancer Center
MSP	Minneapolis
MSWHIS	Mexican or Chicano
MUD	Matched Unrelated Donor
NAC	Nuclear Accident Committee
NACCHO	National Association of County and City Health Officials
NAM	Native American
NAMER	North American
NARR	National Alliance for Radiation Readiness
NCBI	National Center for Biotechnology Information

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NCBM	National Conference of Black Mayors
NCHI	Chinese
NCI	National Cancer Institute
NDMS	National Disaster Medical System
NECEP	New England Center for Emergency Preparedness
NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
NGS	Next Generation Sequencing
NHLBI	National Heart Lung and Blood Institute
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMA	Non-inherited maternal antigen
NIMS	National Incident Management System
NK	Natural Killer
NL	Netherlands
NLE	National Level Exercise
NLM	National Library of Medicine
NMDP®	National Marrow Donor Program
NNSA	National Nuclear Security Administration
NRP	National Response Plan
NST	Non-myeloablative Allogeneic Stem Cell Transplantation
NYC	New York City
OB	Obstetrician
OB/GYN	Obstetrics & Gynecology
OCP	Operational Continuity Planning
OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
OHRP	Office of Human Research Protections
OIT	Office of Information Technology
OMB	Office of Management and Budget
ONR	Office of Naval Research
OPA	Office of Patient Advocacy
P2P	Peer-to-Peer
PA	Presence/Absence
PBMC	Peripheral Blood Mononuclear Cells
PBSC	Peripheral Blood Stem Cell
PCR	Polymerase Chain Reaction
PED	Pedigree
PI	Principal Investigator
POI	Procedures of Interaction
PP	Pseudopatient

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PSA	Public Service Announcement
PT	Proficiency Testing
QAMS	Quality Assurance Membership Services
QARM	Quality Assurance and Risk Management
QC	Quality control
QR	Quick Response
R	Race Pair
R&D	Research and Development
RCC	Renal Cell Carcinoma
RCI	Resource for Clinical Investigations
RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
RD Safe	Related Donor Safety
REAC/TS	Radiation Emergency Assistance Center/Training Site
RED	Radiological Exposure Devices
REDMO	Spanish Bone Marrow Donor Registry
REMM	Radiation Event Medical Management
REMPAN	Radiation Emergency Medical Preparedness and Assistance
REST	Representational State Transfer
RFA	Request for Application
RFP	Request for Proposal
RFQ	Request for Quotation
RG	Recruitment Group
Rh	Rhesus
RITN	Radiation Injury Treatment Network
ROC	Receiver Operating Characteristics
RSSA	R-Shiny Search Application
RT-PCR	Reverse Transcriptase-Polymerase Chain Reaction
SAA	Severe Aplastic Anemia
SAP	Single Amino-Acid Polymorphisms
SBT	Sequence Based Typing
SCAHIS	South/Central American Hispanic
SCAMB	Black South or Central America
SCD	Sickle Cell Disease
SCSEAI	Southeast Asian
SCT	Stem Cell Transplantation
SCTOD	Stem Cell Therapeutics Outcome Database
SEARCH	Page 10
SFVT	Sequence Feature Variant Type
SG	Sample Group

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SHF	Synthetic Haplotype Frequency
SIRE	Self Identified Race and Ethnicity
SLCBB	St. Louis Cord Blood Bank
SLW	STAR Link® Web
SMRT	Single Molecule, Real-Time
SNP	Single Nucleotide Polymorphism
SNS	Strategic National Stockpile
SOA	Service Oriented Architecture
SOP	Standard Operating Procedure
SQL	Structured Query Language
SRA	Sequence Read Archive
SRB	Survey Research Group
SRG	Survey Research Group
SSA	Search Strategy Advice
SSO	Sequence Specific Oligonucleotides
SSP	Sequence Specific Primers
SSOP	Sequence Specific Oligonucleotide Probes
SSRS	Sample Storage Research Study
STAR®	Search, Tracking and Registry
SVM	Support Vector Machine
SWOG	Southwest Oncology Group
TBI	Total Body Irradiation
TC	Transplant Center
TCE	T-cell Epitope
TCR	T-cell Receptor
TED	Transplant Essential Data
TNC	Total Nucleated Cell
TNCC	Total Nucleated Cell Count
TRM	Transplant Related Mortality
TSA	Transportation Security Agency
TTY	Text Telephone
TU	Temporarily Unavailable
UCB	Umbilical Cord Blood
UCBT	Umbilical Cord Blood Transplant
UCSF	University of California – San Francisco
UI	User Interface
UML	Unified Modeling Language
UNK	Unkown
URD	Unrelated Registry Donor

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US	United States
USAID	United States Agency for International Development
USID	Unique System Identifier
USIDNet	US Immunodeficiencies Network
USB	Universal Serial Bus
UTR	Untranslated Region
VCF	Variant Call Format
VIET	Vietnamese
VP	Vice President
VPN	Virtual Private Network
WBMT	Worldwide Network for Bone Marrow Transplantation
WC	Working Committees
WebEOC®	Web-based Emergency Operations Center
WGA	Whole Genome Amplification
WH	White
WHO	World Health Organization
WMDA	World Marrow Donor Association
WU	Work-up
XML	Extensible Markup Language
ZKRD	Zentrales Knochenmarkspender – Register für die Bundesrepublik Deutschland
7 AAD	7-Aminoactinomycin D